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VIA FEDERAL EXPRESS

The Honorable Mark McClellan, M.D., Ph.D., Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, DC 20201
Attention: CMS-1325-P

Re: **Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B: Proposed Rule**

Dear Dr. McClellan:

The National Patient Advocate Foundation (NPAF) is a non-profit organization dedicated to improving access to health care services through policy reform. The advocacy activities of NPAF are informed and influenced by the experience of patients who receive counseling and case management services from our companion organization, the Patient Advocate Foundation (PAF), which specializes in mediation for access to care, job retention, and relief from debt crisis resulting from diagnosis with a chronic, debilitating or life-threatening disease. In fiscal year July 1, 2003 to June 30, 2004, PAF received 3.2 million requests for information and/or direct professional intervention in the resolution of access disputes.

On behalf of the people with cancer we serve, we are writing in response to the Centers for Medicare and Medicaid Services (CMS) proposed rule regarding the Competitive Acquisition Program (CAP) for drugs and biologicals under Medicare Part B (the Proposed Rule).[1] NPAF applauds Congress and CMS for recognizing that some oncology practices may have difficulty managing the financial burdens and risks associated with buying and billing for drugs under a reimbursement methodology based on Average Sales Price (ASP). We also commend their efforts to offer physicians the option of an alternative approach structured to permit the provision of in-office chemotherapy services without requiring an investment in drug inventories or the collection of drug copayments. CAP with appropriate design and effective

[1] 70 Fed. Reg. 10745 (Mar. 4, 2005).

implementation may help protect patient access to community-based cancer care and critical drug therapies.

To help CMS successfully implement the CAP, NPAF offers the following recommendations.

I. Ensure the Adequacy of Reimbursement for Drug Administration Services

Issue Identifier: Categories of Drugs To Be Included Under the CAP

The CAP will not be a viable option unless the payment physicians receive for the professional services associated with the administration of drugs is adequate to cover their costs. NPAF recognizes that CMS substantially increased reimbursement for chemotherapy-related drug administration services in 2004 and further refined payment rates in 2005. We remain concerned, however, that the rates do not yet fully reflect resource utilization and costs associated with these professional services. The situation is made more troubling because, contrary to CMS' expectations, NPAF anticipates the CAP to significantly increase the complexity of the pharmacy management services physicians must provide. For example, under the CAP, changes in individual treatment plans will have to be monitored carefully to ensure that new prescriptions are communicated to the CAP vendor in a timely manner. Physicians also will have to manage patient-specific inventories of drugs, routinely file claims for drug administration services within 14 days, and appeal every denied drug administration claim under a newly revamped appeal procedure that mandates increased upfront preparation.[2] Under the ASP reimbursement system, a physician need not shoulder these burdens.

NPAF believes that the practice expense component of the temporary "G-codes" established to pay for chemotherapy-related drug administration services in 2005 may be inadequate to cover the cost of chemotherapy administration services due to the issues of difficulty in coordinating secondary payer billing electronically and confusion in physician practices about handing G code billing. Two studies conducted for the Global Access Project quantify key problems responsible for the underpayment for drug administration services that continue to plague oncologists.

The analysis reported by The Moran Company in a study entitled "Practice Expense Reimbursement for Cancer Care Services – Changes in Oncology Practice: 2004-2005" (copy attached) shows that CMS's methodology for blending practice expense data from the different specialties to set payment rates for various CPT codes results in oncology being a net donor of costs to other specialties because oncology practice expenses are substantially higher than those of all other specialties. The 2005 payment rates set for the drug

[2] 70 Fed. Reg. 11419 (Mar. 8, 2005).

administration G codes systematically underpay oncologists for in-office chemotherapy services simply as a result of the blending across all speciality physician pools for determination of average reimbursement for speciality physicians.

In NPAF's view, the practice expense component of the existing drug administration codes also fails to reflect the full cost of pharmacy management under the current buy- and-bill model. Those costs were recently quantified – to NPAF's knowledge, for the first time – in another study conducted for the Global Access Project entitled "Documenting Cost of Pharmacy-related Services in Community-based Oncology Practices" prepared by the Pharmacotherapy Outcomes Research Center, University of Utah (copy attached). The study found that the average cost of drug handling services under the buy-and-bill model is $36.03 per chemotherapy administration for the services involved in preparing the drug for administration from the point the drug is delivered to the provider to the point of patient administration. If physicians were forced to manage patient-specific drug inventories under CAP, we suspect these costs might increase.

If CMS wants CAP to offer physicians a viable choice between buying and billing for Part B drugs or having those drugs furnished to their practices by specialty pharmacies selected through competitive bidding, it must take steps to ensure that drug administration payment rates associated with the temporary G-codes for drug administration, or their permanent CPT code counterparts, are adjusted upward in 2006 to more accurately reflect pharmacy management costs and undiluted practice expenses incurred by physicians in the oncology specialty. Otherwise, inadequate reimbursement for professional services may cause oncology practices to shutter their chemotherapy suites and force cancer patients back to hospitals to receive chemotherapy.

In addition, until CMS can implement a prompt process for assigning product-specific HCPCS to new drugs and biologicals, CAP vendors must be required to furnish all drugs classified under the miscellaneous J Codes to ensure that Medicare beneficiaries have access to improved treatment options, as they become available. As a practical matter, new drugs may have missed the window for applying for a HCPCS code, or not otherwise have been assigned a HCPCS code, and must, therefore be billed under the miscellaneous J Code. The essential purpose of the miscellaneous J Codes is to provide a reimbursement mechanism for new drug therapies until they can be assigned a specific HCPCS code. The Proposed Rule provides no information on how vendors should account for "not otherwise classified" drugs when they submit their bids. Accounting for them as a group under the miscellaneous codes seems unworkable since prices and utilization can vary widely within this group of products. CMS should clarify in the Final Rule how bids for these products should be structured and how they will be assessed. Further

guidance on how not otherwise classified products will be reimbursed under CAP is also essential.

II. Implement Safeguards to Protect Patients with Financial Hardship

Issue Identifiers: Contracting Process – Bidding Entity Qualifications
Contracting Process – Contract Requirements

NPAF is concerned about the potential for CAP vendors to stop providing drugs to patients who do not remit coinsurance payments in a timely manner. Patients often have personal relationships with their physicians, and highly value those relationships. Still, many physician practices struggle with bad debt, generally collecting only about half of the coinsurance owed them. The CAP vendors likely will have more difficulty collecting. They will not have personal relationships with the beneficiaries they are billing, but rather will be a "faceless," invisible entity that patients do not know or even associate with the care they received. Moreover, the CAP vendors will not have the ability to seek payment at the end of a chemotherapy session. Rather, they must wait until Medicare pays their drug claims under a complex claims processing system that involves the matching of vendor claims with physician claims submitted to different carriers. Under the best of circumstances, CAP vendors will not be able to initiate the coinsurance collection effort through bills sent by mail until a month or more after the beneficiary received a drug administration service.

NPAF believes that patients who often are teetering on the brink of insolvency because of the high cost of cancer care – costs that can include not only deductible and coinsurance payments for drugs and professional services that are not covered by secondary insurance, but also lost income resulting from work interruptions, transportation costs, custodial care expenses, costs associated with changed dietary needs, etc. – may be inclined to place a relatively low priority on paying their CAP vendor. NPAF fears that these difficulties may result in cessation of drug deliveries for patients who are in arrears.

We are not alone in this concern. The Practicing Physicians Advisory Council has proposed that CMS should require CAP vendors to advance credit to and negotiate payment plans with patients unable to afford the coinsurance payments. NPAF strongly seconds that recommendation. NPAF also would go a step further. In 2002, 5% of the calls received by the Patent Advocate Foundation involved requests for cost-sharing assistance. In 2003, requests for financial assistance increased to 42% and, in 2004, those requests exploded to 70% of all calls. Therefore, NPAF asks CMS to require vendors to develop procedures for assessing financial need and waiving cost-sharing for non-Medicaid eligible beneficiaries with incomes up to 150% of the

federal poverty level or partially waiving cost-sharing on a sliding scale for beneficiaries with incomes between 150% and 250% of federal poverty. Vendors also should be required to have social workers on staff or make other appropriate arrangements to assist patients explore payment options and safety net programs available to them. CMS should assess the adequacy of a CAP vendor's needs assessment and coinsurance waiver plans as part of its review of the vendor's quality, service, and financial performance qualifications, and should only consider bids from vendors with plans that are sufficiently generous to ensure reasonable patient access. We would expect that many CAP vendors would include referrals to advocacy organizations like the Patient Advocate Foundation in their access safeguard programs.

III. Specify Delivery Requirements Consistent with Timely Access to Needed Drugs

Issue Identifier: Operational Aspects of the CAP – Bidding Entity Qualifications
Statutory Requirements Concerning Claims Processing

Many drug regimens, particularly cancer treatments, must be administered on precise schedules. For patients, it is crucial that their physicians can provide the right therapy at the right time. Consequently, CMS should modify the Proposed Rule to provide additional assurances that patients will have timely access to the drugs they need. NPAF has three recommendations in this regard.

First, when evaluating a prospective CAP vendor, CMS should collect information on the vendor's personnel statistics, warehouse and dispensing capacities, distribution center locations, and inventory sourcing relationships and compare it to pre-established criteria that ensure the vendor can handle the dispensing load and time pressures it will be expected to manage. In NPAF's view, quality patient care demands that vendors have arrangements with a broad network of local pharmacies. Otherwise, the CAP vendors may be unable to make routine and emergency deliveries in time frames adequate to meet patient needs. Disease management requires flexibility and immediate changes in Medicaid protocol when necessary due to sudden changes in the patient's disease state. We note that the Department of Defense and CMS have developed criteria for assessing the adequacy of retail pharmacy networks under Tricare and the Part D rule[3] that will be implemented in 2006. We see no reason why CMS cannot take the same approach to establishing acceptable criteria for CAP vendor delivery networks.

Second, CMS must move beyond the minimum delivery standard set forth in the Proposed Rule. It simply is not sufficient to permit CAP vendors to ship only 5 days a week in a manner that insures routine deliveries in 1-2 business

[3] 70 Fed. Reg. 4193 (Jan. 28, 2005).

days and emergency deliveries the next business day for orders submitted before 3 pm. Rather, to ensure adequate patient access, CAP vendors must be required to ship 7 days a week and provide routine next-day drug deliveries, with same day or even twice daily "emergency" deliveries.

Third, CMS also should liberalize the emergency replacement and resupply procedures available to physicians who select CAP. The Proposed Rule would allow a physician to use drugs and biologicals from the physician's own inventory and then resupply the inventory with products acquired under the CAP only if the physician demonstrates that: (1) the drugs were required immediately; (2) the physician could not have anticipated the need for the drugs; (3) the vendor could not have delivered the drugs in a timely manner; and (4) the drugs were administered in an emergency situation.[4] CMS does not propose a definition of an "emergency" for purposes of accessing applicable delivery standards or for determining when the resupply option would be available, but asks for comment on how it should be defined.

To avoid interruptions in patient care, CMS must make CAP more flexible. Although physicians often will be able to plan a patient's course of treatment far enough in advance to order drugs through the CAP vendor, an oncologist cannot always anticipate a patient's response to a particular chemotherapy regime or need for various support therapies. Patient responses to toxic regimens are not always predictable and advances in life-threatening disease status can be sudden. Physicians also cannot predict adverse reactions to a drug. Nor do they know when a scheduled delivery from their CAP vendor will be delayed.

The delivery standards and resupply procedures in the Proposed Rule could force a patient who is in the physician's office needing treatment to go home and wait one or more days for a CAP order to arrive. Not only would this unacceptably delay care, in many instance, it would be burdensome, or even impossible, for a patient and perhaps also for the family member or caregiver assisting the patient to return. By having to return to the physician's office on another day, the patient would endure additional hardship as a result of the difficulty in traveling to and from the provider's office and, perhaps, the need to take additional time off from work for the caregiver. The patient also would incur additional coinsurance expenses for an extra physician visit. The primary issue is irreversible patient deterioration due to delay.

To address the timing problem under CAP, a physician should, in most instances, be able to revise a patient's treatment plan in the morning and still take delivery of needed drugs on the day the patient presents so that patients have the option of waiting a few hours rather than returning another day. We recognize that implementing this option would require a CAP vendor to have an extensive network of relationships with local pharmacies throughout its

[4] Proposed 42 C.F.R. § 414.906(e), see also 70 Fed. Reg. at 10755.

service area, but we view an expansive delivery network as essential to adequate, timely patient care. By requiring CAP vendors to use a networked delivery structure, CMS would also cut down on the need for physicians to rely upon their own inventories and the Proposed Rule's resupply option. NPAF views this as an important consideration because practices that treat primarily Medicare patients may not maintain sufficient inventories after selecting CAP to satisfy all patient care needs. That said, NPAF also believes that patients and physicians should have the choice of immediate access if the physician is able to furnish the needed therapy from his or her own stock without concern about after-the-fact denials of the drug replacement obtained from the CAP vendor under an inappropriate, rigid definition of "emergency" that is not consistent with that of the treating physician. Otherwise, CAP vendors, not physicians, will be dictating medical decisions for patients. This is simply unacceptable from a patient care perspective.

As currently proposed, the replacement and resupply provisions are burdensome not only for patients, but also for physicians. When a scheduled treatment is not delivered on time or when a patient's treatment plan must be changed on the day of a visit, the proposed strict, emergency-only criteria means that the physician's office will have to spend time rescheduling the patient's appointment. Although we question the legality under applicable state pharmacy laws of redirecting drugs prescribed for one patient to another, the Proposed Rule also would obligate a physician who wants to use the resupply mechanism to notify the CAP vendor about the change in the patient's treatment plan and negotiate redirection (or destruction if redirection is not feasible) of the unused drug. In addition, the physician will be expected to maintain documentation showing that all of the criteria for emergency replacement and resupply were met, and will be subject to post-payment review and recoupment if the local carrier concludes that the records do not justify resupply through the CAP vendor. To add further to the administrative burden of the proposed resupply procedure, physicians will be required to appeal denials of care provided in good faith under the resupply mechanism if post-payment reviews lead to recoupments.

For purposes of setting standards both for timely emergency delivery and for the resupply option, NPAF urges CMS to define "emergency" broadly to mean any situation a physician views as requiring immediate attention. If the agency wants to limit the use of the resupply option, it could set twice daily delivery as the emergency delivery standard for all CAP vendors and then require physicians to contact their vendor and document that needed drugs could not be delivered the same day as a condition precedent to drug replacement under the Final Rule's resupply option. If CMS is indifferent to whether the CAP vendor dispenses the drug actually administered or furnishes it through the resupply mechanism, CMS could simply eliminate the requirement that drugs be administered in an emergency situation before a selecting physician can use a drug from his or her inventory. Either

modification would better reflect the unpredictable nature of patient care, and the reality that delaying care, even for a day, would be contrary to a patient's best interests.

IV. Preserve the "Furnish as Written" Option, but Reduce its Administrative Burdens

Issue Identifier: Operational Aspects of the CAP - Claims Processing Overview

Under the Proposed Rule, a CAP vendor must provide at least one drug or biological within each Healthcare Common Procedure Coding System (HCPCS) code, but need offer just one National Drug Code (NDC) product per HCPCS. As a result, only generic products will be available for some HCPCSs. In a few payment categories (e.g., the HCPCSs for intravenous immune globulins or growth hormone), only one of several single-source products will be offered. As a result, on occasion, the specific formulation needed by a patient might not be available from the physician's CAP vendor. In these cases, CMS proposes to allow physicians to "furnish as written" by purchasing the drug from another source and billing Medicare using the average sales price (ASP) methodology, even though the physician has otherwise elected to participate in the CAP.[5] This procedure provides a mechanism for ensuring that physicians, not CAP vendors, are making medical decisions regarding the appropriate therapies for patients. NPAF commends CMS for including this provision in the Proposed Rule, and recommends that it be preserved in the Final Rule.

We recommend that CMS reduce the administrative burden associated with this option to the extent possible. As currently proposed, physicians that write furnish-as-written orders will have to maintain documentation supporting why the particular drug selected was medically necessary. Although physicians always must be prepared to support the medical necessity of their orders, the decision has not historically turned on a comparison of the clinical appropriateness of one drug within a HCPCS code with that of any another. Moreover, a furnish-as-written order could be subject to post-payment review that would, if denied, trigger an obligation to appeal. We are concerned that frequent audits would increase the burdens associated with participating in the CAP, thereby discouraging physicians from using the furnish-as-written option when medically appropriate.

NPAF is also concerned that physicians who use the furnish-as-written option for the good of a patient might not be able to obtain optimal pricing when they buy directly from a wholesaler because they have become lower volume purchasers. The Final Rule should address this concern by providing for drug

[5] 70 Fed. Reg. at 10755.

reimbursement under the furnish-as-written option at documented actual acquisition cost whenever the cost of a furnish-as-written drug exceeds ASP+6%. After all, the physician's lack of bargaining power in this situation would be attributable, at least in part, to his or her decision to select CAP. The furnish-as-written option was created by CMS, without benefit of a specific mention of the procedure in Social Security Act §1847B, to protect patient rights under a statutory mandate requiring the CAP vendor to work from drug list (one NDC per HCPCS) that cannot be expanded through beneficiary appeal. In the absence of statutory instructions about reimbursement under the regulatory procedure, CMS should be able to set payment levels in any manner it deems consistent with Congressional intent to match drug payments with acquisition costs and should not feel bound to rely upon ASP + 6% as the only acceptable reimbursement metric for furnish-as-written drugs.

* * *

NFAP appreciates this opportunity to comment on the Proposed Rule, and looks forward to working with CMS to protect Medicare beneficiaries' access to appropriate drug therapies.

Respectfully submitted,

Nancy Davenport-Ennis
Chief Executive Officer

Attachments

cc: Deborah Kamin

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American Medical Association

Physicians dedicated to the health of America

APR 26 2005

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April 26, 2005

Mark McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
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P.O. Box 8010
Baltimore, MD 21244-8010

Re: Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B; Proposed Rule; 70 Fed. Reg. 10745 (March 4, 2005); File Code CMS-1325-P

Dear Dr. McClellan:

The American Medical Association (AMA) appreciates the opportunity to submit our comments concerning the Centers for Medicare and Medicaid Services' (CMS) proposed rule to implement a competitive acquisition program (CAP) in the Medicare Program, *Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B; 70 Fed. Reg. 10745* (March 4, 2005).

Overview of the CAP

The AMA appreciates CMS' efforts in developing a proposal to implement a new and complex competitive bidding program for Part B drugs. This program, which would become an alternative to payments based on the average sales price plus six percent, is untested and there is uncertainty about what the final program will look like. Therefore, the AMA recommends that CMS issue an interim final rule with comment rather than a final rule so that the physician community and other stakeholders can submit additional comments on the CAP. As noted later in this document, we also believe that, at a minimum, CMS should require vendors to offer all the drugs that physicians have been unable to purchase at 106% of the Average Sales Price (ASP). We would like to see additional discussion regarding the legal liability of the vendors in cases where drugs have been damaged or tampered with in the delivery process. In addition, CMS should include a plan for protecting beneficiaries who cannot reimburse the vendor for the patient copays associated with these drugs.

The AMA is very concerned that the combined impact of cuts in drug payment rates and scheduled across-the-board cuts related to the Sustainable Growth Rate (SGR)

will force many physicians to stop providing these drugs in their offices. In that event, patients will be forced to seek this care from hospitals, where they are likely to face higher costs than they do currently. With that in mind, we urge the Administration to take an active role in averting projected cuts of 26% in the physician conversion factor over the next six years, including removal of physician-administered drugs from the SGR, retroactive to the SGR base year.

Further, CMS should not include CAP prices in determining ASPs. To do so would set up a perpetual downward spiral as CAP prices lead to reductions in ASPs, which then lead to additional reductions in the next year's CAP prices, and so on. Physicians already find it impossible to purchase some drugs at the ASP. Further reductions created by the inclusion of yet another discounted purchaser will only exacerbate the current problems, eventually forcing all physicians into the CAP and greatly diminishing their ability to determine which drugs are provided to their patients and to control the quality of those drugs.

Categories of Drugs to be Included under the CAP

Section 303(b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) establishes a competitive acquisition program (CAP) for the acquisition and payment for Part B covered drugs and biologicals furnished on or after January 1, 2006. Beginning January 1, 2006, physicians will have a choice between acquiring and billing for Part B covered drugs under the Average Sales Price (ASP) drug payment methodology or electing to receive these drugs from vendors selected for CAP under a competitive bidding process. The key purposes of the CAP are to provide an alternative method for physicians to obtain Part B drugs to administer to their Medicare patients and to reduce drug acquisition and billing burdens for physicians. In implementing the CAP, CMS is required to establish categories of competitively biddable drugs and biologicals and to phase in the program with respect to those categories, as it deems appropriate.

With respect to the scope of the CAP, CMS is proposing to limit the CAP, at least initially, to drugs administered in physician offices – e.g., those drugs that are administered as "incident to" a physician's service – even though the statute provides a broader definition of "competitively biddable drugs and biologicals" to include drugs administered through durable medical equipment (DME) (for example, inhalation drugs) with the exception of DME infusion drugs, and some drugs usually dispensed by pharmacies (for example, oral immunosuppressive drugs). The AMA agrees with this approach. CMS can always re-examine the scope of the program after the CAP is implemented and there is enough data to study how the program is working.

CMS seeks comments on the different options it is considering for phasing in the CAP. In terms of the drugs covered by the program, one option would be to include all drugs furnished incident to a physician's service; a second option would be start with a limited set of drugs typically used by oncologists; and a third option would be to begin with a smaller number of drugs used by other specialties.

Previously, the AMA took the position that because a competitive bidding system for physician administered drugs is new and untested, CMS initially should allow competitive bidding for only a few drugs. However, we can see both sides of the phase-in issue. For example, beginning with specialties that use fewer Part B-covered drugs would limit the scope of the initial program and provide an opportunity for the agency and stakeholders to identify issues and problems before phasing in larger drug classes such as those used by oncologists. Likewise, beginning with drugs used by a single specialty, i.e., oncology, would allow CMS to deal with a more limited and homogeneous set of implementation issues before expanding the CAP. On the other hand, as CMS points out in the preamble of the proposed rule, beginning with a limited program might be too narrow in scope to really be useful in identifying issues and problems. Another disadvantage is that restricting the list of drugs or specialties could also limit the number of bidders.

Most important, limiting the scope of the program initially would not fulfill Congressional intent of providing physicians with an alternative to ASP for acquiring Part B drugs beginning on January 1, 2006. Therefore, we have concluded that CMS should make the CAP available to all physicians for all drugs that are furnished incident to a physician's service beginning in 2006. If, however, CMS decides to phase in the CAP, then at the very least, CMS should include all of the "problem" drugs – e.g., the Part B drugs that physicians have reported are unavailable at ASP.

There have been widespread reports of difficulties with some drugs, including several of the drugs used for treating bladder cancer as well as Levaquin, rocephin, and saline solution. Even when the difference between the ASP and the physician's purchase price appears to be rather modest, losses can mount up quickly if the drug is used in large quantities. It is our understanding that CMS's Physicians Regulatory Issues Team (PRIT) has identified at least 40 "problem" drugs. If the intent of the CAP truly is to provide a safety net, these drugs should all be included in the initial CAP offerings.

The AMA also requests that if CMS chooses to phase in CAP one category of drugs at a time, the opportunity to acquire drugs through the CAP should be available to any specialty that requires the drug for any purpose, including off-label use. For example, the rule suggests that CMS might begin by covering the most prevalent drugs administered by oncologists, including infliximab (Remicaide). The rule does not specify whether other specialties (rheumatologists and gastroenterologists) who use this drug to treat other diseases (rheumatoid arthritis and Crohn's Disease) would also be permitted to participate in the CAP under this option. We see no reason to limit the CAP alternative only to oncologists in this instance and believe the rule needs clarification on this point.

Competitive Acquisition Areas

CMS seeks comment on possible approaches for defining the competitive acquisition areas (CAA) required by statute for the CAP. The basic options are creating a national CAA,

regional CAAs, or statewide CAAs; each approach has pros and cons. While we do not have a particular preference about the competitive acquisition areas, we urge CMS to fully implement the CAP nationwide, e.g., in all acquisition areas, from the start of the program.

Operational Aspects of the CAP

Statutory Requirements Concerning Claims Processing

The statute provides that a vendor may not provide drugs to a physician participating in the CAP unless the physician submits a prescription for each patient to the vendor. For purposes of the CAP, CMS is proposing to interpret "prescription" to include a written order submitted to the vendor. The proposed rule does not specify what format(s) may be used, although in the preamble, CMS indicates that the order may occur in a variety of HIPAA-compliant formats, such as by telephone with a follow-up written order. It is important that the process for ordering drugs be as user-friendly as possible, and structured to be as similar as possible to the way a physician currently orders drugs. The process for ordering drugs should include phone, fax, and the internet. CMS should specify in the final rule that these formats may be used.

Claims Processing Overview

1. Vendor's obligation to fill order

CMS sets forth in detail proposed requirements for both physicians and vendors participating in the CAP. However, although physicians are required to submit a written order to their CAP vendor in order to acquire drugs, there is no requirement that a vendor must fill every valid (e.g., properly completed) order received from a physician. While this might be implicit, we believe this obligation on the vendor's part should be made explicit in the final rule.

2. Information Required with Order

CMS seeks comments on the information required to be part of the drug order. While information about the patient's secondary insurance, if any, is appropriate, much of the other information, such as "frequency/instructions," anticipated date of administration, and "additional patient information, such as date of birth, allergies, Ht/Wt/ICD-9, etc," is either unnecessary or inappropriate.

Information about "anticipated date of administration" should be changed to allow a range of dates on which administration is anticipated for a particular patient. It is not always possible to predict the exact date on which drugs will be administered. A patient's schedule for therapy often changes based on the patient's condition, or because a patient cancels or reschedules an appointment. It is duplicative to ask for information about "Frequency." The vendor does not need such information to fill the order and can obtain this information

from the claim form filed by the physician. Finally, we do not understand why the physician should be required to provide "additional patient information."

3. Filing of Physician Drug Administration Claim and Vendor Payment

Under the statute, Medicare payment to the vendor, and any applicable deductible and coinsurance, is conditioned upon actual administration of the drug to the patient for which it was ordered. However, CMS is going beyond this statutory requirement by proposing that payment to the vendor also would be dependent upon the filing of the drug administration claim by the physician and approval of the physician's claim by the CMS claims processing system. Moreover, the physician would be required to submit all claims for drug administration services within fourteen days of the date of service. Filing within such a tight time frame would be impractical and difficult for many practices. We recommend instead that physicians should have at least 30 business days after the date of drug administration to submit claims.

We also question why payment to the vendor should have to wait not only until the physician has filed the drug administration claim, but also until the claim has been approved. CMS indicates in the preamble that it is considering, but not proposing at this time, making partial payments to vendors. The AMA favors making partial payments available to vendors. This would encourage greater participation in the CAP by both vendors and physicians by preventing cash flow problems for vendors and eliminating potential disputes between physicians and vendors over how rapidly the physician must file their claims. However, physicians should not be involved in any reconciliation that might arise between the vendor and the CMS claims processing carrier.

4. Timely deliveries and emergencies

The AMA supports CMS' proposal that in emergency situations, drugs acquired under the CAP could be used to resupply inventories of drugs administered by physicians as long as all of the following conditions are met: 1) The drugs were required immediately; 2) The physician could not have anticipated the need for the drugs; 3) The vendor could not have delivered the drugs in a timely manner; and 4) The drugs were administered in an emergency situation. With respect to how to define timely delivery for emergency drug shipments, CMS proposes that emergency drug orders would be furnished on the next day for orders received by the vendor before 3 p.m., but seeks comment on the feasibility of providing same-day deliveries for emergency orders (preamble at page 10760).

To prevent misunderstanding and possible audits and repayment demands in the future, CMS should lay out more detailed criteria on what the agency would regard as an emergency. It seems clear that many patients with infectious diseases often would need immediate treatment and even next day or 24-hour delivery would not be prompt enough in these situations. However, there are many other situations where delayed administration is not life-threatening but still would impose a substantial hardship or lead to unreasonable

delays in the delivery of effective therapies. For example, some patients may travel three to four hours for their treatment. Others may need immediate care to relieve intense pain or prevent a particularly aggressive cancer from spreading further. Is this an emergency or will these patients be told to come back another day if the drug they need is not available because it is this patient's first visit? What if the vendor ***could*** have delivered the drug but ***didn't*** due to some glitch in the administrative process?

One possibility CMS should consider is the creation of a group of physicians and patients to help flesh out the definition of an emergency. In the meantime, the AMA believes that emergency orders should be filled on a same-day basis when possible. If that is not possible, physicians should be allowed to buy the needed drug from a source other than the CAP vendor or take it from existing stock. They should then have two options: (1) order the drug from the vendor to replace their private stock or (2) bill for the replacement drug using the ASP methodology.

The latter option could be modeled after the existing "furnish as written" provision, which allows physicians to "obtain a drug under the ASP methodology" in certain situations. This would reduce administrative hassles associated with replenishing the physician's supply and potentially avoid unnecessary hospital stays for patients that could have been treated more cost effectively in physicians' offices. In addition, care must be taken to ensure that whatever mechanism is implemented is of minimal burden to both the physician and patient.

5. Disposition of Unused Drug

The proposed rule provides that if a drug is not administered on its "anticipated" date, the physician should notify the vendor and "reach an agreement on how to handle the unused drug, consistent with applicable State and Federal law." While the preamble explains the process to be followed if agreement is reached that the drug could be maintained in the physician's inventory, there is no guidance, in the preamble or the rule, about what happens if this is not the resolution. If the vendor requires the physician to return the unused drug, is the physician required to comply? If the physician sends the drug back, is the physician allowed to charge the vendor for shipping fees? Could the vendor require the physician to mitigate the vendor's loss by offering to administer the drug to another Medicare patient? These questions need to be addressed in the final rule.

6. Vendors and Drug Categories

We agree with CMS that physicians who elect to participate in the CAP would continue to bill their local carrier for drug administration. We also support allowing physicians to choose the categories of drugs they wish to obtain from vendors, and agree that for those drugs that are not included in the CAP and for drug categories that the physician does not select, the physician would continue to bill and be paid under the ASP methodology.

7. Payment for Administrative Costs

We disagree with CMS's decision not to make a separate payment to physicians for the clerical and inventory resources associated with participation in the CAP program. On page 10755 of the Preamble, CMS states "We do not believe that the clerical and inventory resources associated with participation in the CAP exceed the clerical and inventory resources associated with buying and billing drugs under the ASP system." We question how CMS came to such a conclusion. Although participating in the CAP means that physicians will not have to purchase drugs and bill Medicare patients for co-payments, there are many administrative requirements in CAP that will necessitate just as many, if not more, clerical and inventory resources for physician practices.

Ordering drugs under the CAP could cost significantly more than under the reimbursement system. Under the reimbursement system, physicians generally maintain an inventory for each type of drug and order additional units when the inventory falls below a certain level. For example, oncologists often use an automated storage and inventory control system that tracks the remaining amount of each drug. By contrast to this relatively simple method of ordering in bulk, the CAP requires orders to be submitted to the vendor for each patient, and those orders would need to provide significant patient-specific information instead of simply the number of units requested.

The proposal would also require a different type of inventory system than practices currently use. An inventory record would have to be created for each drug. The identity of each drug received from the CAP vendor would need to be entered into a record together with the identifying number furnished by the CAP, and a further entry into the inventory record would be required when the drug was administered. We have been advised by some of the medical specialty organizations that physicians currently do not maintain similar inventory records, and the additional work involved would appear to be substantial.

Storage costs would be at least as large under the CAP as under the reimbursement method, and storage may be more difficult to manage. Although the proposal states that the CAP drug inventory would not need to be segregated from other inventory, there may need to be some form of segregation so that the office staff can ascertain the amount of inventory available for non-Medicare patients. For example, if a physician has ten vials of a particular drug on hand, it will not be clear from visual observation whether all of the vials have been received from the vendor for Medicare patients or whether part of the inventory is available for non-Medicare patients.

At the billing stage, there would be more work under the CAP than under the reimbursement method. The content of the claims would be identical in most respects under both systems, but the CAP claim would need to include a prescription number for each of the drug codes billed. Retrieving the prescription number for each drug and including it in the claim would be significant additional work beyond what is now required. For physician practices not currently using prescription numbers, additional non-reimbursable costs will be incurred to make the necessary software changes to submit these data elements to Medicare.

CMS states in the preamble that it is not their intention to restrict the physician's flexibility when ordering a drug from a CAP vendor or to require that a physician would order drugs differently from a CAP vendor than the way a physician would order from a non-CAP vendor. We understand that in developing this proposal, CMS is constrained by statutory requirements and the existing Medicare claims processing rules. However, CMS's proposal would require physicians to order drugs differently under the CAP program.

We urge CMS to simplify claims processing under the proposal as much as possible to alleviate the administrative burden on physicians, and to develop a mechanism to reimburse physicians for any additional administrative costs they incur for participating in the CAP. Such payments should not be included in the SGR or if they are, should be adjusted for in the law and regulation component of the formula.

Dispute Resolution

Under the proposal, only the physician would have appeal rights in the case of claims that are denied for medical necessity or other reasons. If the vendor dispenses drugs and cannot obtain Medicare payment because the physician's claims are denied, CMS is proposing that the vendor should have the right to complain to its carrier if the losses with respect to an individual physician exceed an "acceptable threshold." If that occurs, the carrier will counsel the physician to submit clean claims and to pursue administrative appeal rights on denied claims. If problems persist, the carrier could recommend to CMS that the physician be suspended from the CAP, and CMS would decide whether to do so. CAP vendors would also be required to have procedures to handle complaints about service from physicians and about billing issues from patients.

CMS should clarify the extent of the physician's responsibility to appeal denied claims. The physician's duty should be only to seek review by the carrier (or redetermination by the carrier under the new appeals regulations). Further appeals should be at the discretion of the physician, who should be permitted to weigh the chance of success against the expense and burden of the appeal.

The proposal indicates that beneficiary billing disputes would be handled by the beneficiary first using the vendor's grievance process and, if the beneficiary is dissatisfied with the result, requesting intervention by the vendor's carrier. The carrier would investigate the facts and then facilitate correction to the claim record and beneficiary file.

This process should be made very clear to beneficiaries. CMS should develop standard language that vendors would be required to include in every bill to beneficiaries explaining the grievance process and the method for subsequently appealing any issues to the designated carrier. The information should make clear that the beneficiary's physician is not involved in the billing and has no authority to resolve any disputes.

The proposed rule does not set out a clear mechanism for resolution of disputes related to quality of service or beneficiary billing. The preamble states only that the Medicare carrier will attempt to resolve such disputes if the vendor and the physician or beneficiary cannot. We believe that the process should be more definitive. At a minimum, the carrier should be given a clear mandate to resolve disputes, the process for doing so should be clear and should offer the parties an opportunity to participate in a meaningful way.

Contracting Process – Quality and Product Integrity Aspects

The proposed regulation includes a number of provisions intended to ensure that the vendors provide drugs that meet quality and product integrity standards. We have the following concerns that we urge CMS to address.

1. Vendors should be prohibited from opening drug containers

CMS is authorized by the statute to impose product integrity safeguards. The final rule should deal with the authority of vendors to open drug containers. For example, if a vendor believes that a particular patient's order does not require a full container of drug, the vendor may open a container and dispense only the portion that the vendor believes is necessary by transferring a portion of the drug to another container for shipment to the ordering physician.

Any compromise of package integrity would be unacceptable. Vendors should be clearly required to ship products to physicians in containers that are unopened and otherwise in the same condition as received from the drugs' manufacturers.

2. Return of damaged or suspicious drugs

Physicians should be permitted to return to the vendor without penalty any drug that arrives in damaged condition or whose integrity the physician reasonably believes may have been compromised. The physician should not be required to seek a remedy from the company that delivered the product.

3. Vendors should be required to carry substantial liability insurance

There should be a requirement that vendors carry substantial liability insurance. If vendor errors cause harm to patients, their liability for damages could be substantial. The final rule should require liability insurance in sufficient amount to cover potentially serious adverse events.

4. Vendors should be required to indemnify physicians for any losses they cause

If actions by the vendors in handling the drugs result in injury to patients, it is possible that claims will be made against the physicians who administered the drugs. The final rule should require vendors to indemnify physicians for any losses, damages, and costs

(including attorneys fees) incurred by the physician as a result of the vendor's negligence, errors, or omissions.

5. CMS should audit compliance with and enforce the standards

CMS should take a more affirmative role in determining vendor compliance by, for example, inspecting vendor facilities, monitoring complaints, auditing vendor compliance with time schedules in the regulations, and so forth.

Bidding Entity Qualifications

Under the proposed rule, vendors would be considered covered entities under HIPAA. The AMA believes CMS should clarify whether vendors have the right to sell physician-specific data. If the vendors do have this right, the vendors should be required to disclose their policies on any non-CAP data transfers that they might make so that physicians may take those policies into account before selecting a vendor or signing a CAP election agreement. Similarly, CMS should clarify the extent to which vendors may market to patients.

CAP Bidding Process-Evaluation and Selection

CMS proposes to make adjustments to the vendors' payment schedule on an annual basis. There would be more frequent adjustments in certain cases, such as when a new drug is introduced, but such adjustments would be done only quarterly. The proposal is silent as to when vendors would be obligated to provide newly approved drugs to physicians. CMS should revise the vendor payment schedule as new drugs are approved and require vendors to make such drugs immediately available to physicians. If it is impossible for vendors to do so, physicians should be able to obtain new drugs outside the CAP. Vendors also should be prohibited from making deletions or substitutions in the formulary mid-year.

Physician Election Process

Under the proposal, physicians would annually decide whether to participate in the CAP. If a physician's selected CAP vendor is terminated from the program or leaves the program mid-year, we recommend that physicians should have the option of ending participation in the CAP or choosing another vendor. The proposed rule is silent regarding a physician's right to leave the program or select another vendor mid-year if dissatisfied with a vendor's service. We recommend that the final rule allow a physician to change vendors or leave the program if there is a service problem with a vendor.

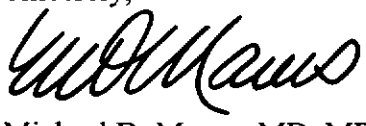
Impact on Patients

Finally, the AMA would like to express its concerns regarding CAP's potential impact on Medicare patients. Co-payments for most of the drugs that will be involved in the CAP are significant. For patients who lack any supplemental coverage, the costs are often

prohibitive. Today, physicians waive the co-payments for a significant number of these patients. However, it seems unlikely that vendors will be willing to absorb this loss. In fact, even those patients who do have supplemental insurance could face substantial difficulties due to possible differences between the drugs covered under these policies and those provided by the vendor. Although the proposed rule does not address this issue, the final rule should lay out a process for dealing with these situations and CMS should monitor the situation closely.

We appreciate your consideration of our comments on the proposed CAP regulation.

Sincerely,



Michael D. Maves, MD, MBA

Privileged and Confidential

April 25, 2005

APR 26 2005

Dr. Mark McClellan
Administrator
Center for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1380-IFC
P.O. Box 8010
Baltimore, MD 21244-1850

Dear Dr. McClellan:

Priority Healthcare Corporation (Priority), a specialty pharmaceutical distributor and specialty pharmacy services provider, is pleased to submit these comments in response to the proposed rule for the competitive acquisition program (CAP) of outpatient drugs and biologicals under Part B ("proposed rule").[1] Priority supports the Centers for Medicare and Medicaid Services' (CMS) efforts to implement the CAP program and seeks to implement the policy goals of the Medicare Prescription Drug, Improvement and Modernization Act (MMA) in a manner that best serves the interests of beneficiaries, providers and taxpayers.

Priority understands that optimal patient care and convenience is the ultimate goal of Congress and CMS, and strongly supports that position. Furthermore, we support CMS in its position that the community physician office setting is the right place to provide most of the drugs covered under this rule with appropriate compensation for administration and delivery of high quality care.

In these comments, Priority seeks to ensure that the CAP program regulations promote optimal patient care and convenience, appropriate reimbursement for physician offices, as well as fair compensation and risk mitigation for CAP vendors. Additionally, we seek to ensure the integrity of products through a logistically sound and operationally efficient distribution model. Finally, we are committed to ensuring compliance with all applicable state and federal laws, as well as appropriately allocating risk among all parties, based upon what each party can directly control.

[1] "Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B," 70 Fed. Reg. 10,745–10,773 (Mar. 4, 2005).

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Introduction to Priority Healthcare

Throughout the past year, we have had the privilege of meeting with many CMS representatives in both formal and informal settings to discuss the CAP program. In these meetings we discussed the uniqueness of our company and proposed model or models with Herb Kuhn, Director of the Center for Medicare Management (CMM), Don Thompson, Amy Bassano, and others within the Centers for Medicare and Medicaid Services (CMS). Through these interactions we feel we have a strong understanding of where CMS wants to take the CAP program, and have provided CMM with our initial impressions of the draft rule, gleaned from interactions with our customers, physicians, health plans, and pharmaceutical manufacturers. The comments within this document are a more thoughtful and deliberate reflection of our concerns as we hope to continue our dialogue with you and your staff as final preparations are made to launch this important program.

As both a specialty distributor (distribution of specialty and biotech drugs to physician offices, clinics, etc. in their "bulk" form, non-patient specific), and a specialty pharmacy (provision of pharmacy services for specialty and biotech products on a patient specific basis, to the physician office or directly to the patient's home), Priority is uniquely positioned to meet the requirements of the CAP program for CMS, physician participants and patients.

Unlike pure distributors, Priority has extensive capabilities and experience in reimbursement services, claims processing and adjudication services. Priority also provides clinical services, including 24/7/365 nursing and pharmacy support, that define comprehensive specialty pharmacy care. To this end, Priority has developed our Caringpaths clinical programs based on core criteria and utilization management protocols specific to best practice standards that are both drug and disease specific. Our Caringpaths care management therapeutic programs help to ensure that patients and physicians are successfully managing these therapies and lead to successful outcomes. Additionally, Priority is an experienced provider of other related patient and physician office support services that include metric based compliance tracking, electronic medical record integration and disease treatment management programs, all of which are a testament to our experience working to build best in class specialty pharmacy programs.

Priority is also distinguished from pure pharmacies as we have extensive expertise in logistics and cost effective distribution systems, augmented by our clear focus and expertise in the specialty channel. Therefore, Priority has significant insight into this market and is uniquely qualified to offer input to CMS on this proposed program, and to potentially work with CMS to craft the type of hybrid solution that may best fit your requirements.

One of the issues that CMS must reconcile within its final rule, is whether vendors are to be distributors (under state wholesaler/distributor licensure), or pharmacies (under state Board of Pharmacy licensure). This distinction is critical to ensure vendor adherence to all appropriate state and federal laws. Our assumption, based on the patient specific requirements of this program, is that pharmacy licensure is required, along with the 3 year experience requirement as outlined in the proposed rule.

Comments

Adjudication Risk

Under the proposed model, CAP vendors must wait until the physician's claim for drug administration is submitted before they can submit a claim for reimbursement. This is problematic from both a time value of money perspective and for the potential adjudication risk. While the time value of money is clearly an economic cost, the greater risk is that the CAP vendor may be penalized for untimely or inaccurate submission of the administration claim, a circumstance that is completely out of the control of the CAP vendor.

Credit Risk

Additionally, under the existing rule, the CAP vendor's claim must be matched to the physician's claim before a bill for coinsurance or a deductible can be generated. This situation is further exacerbated with respect to the collection of beneficiary co-payments. Every day that transpires without collecting a co-payment significantly impairs the contractor's ability to realize the full price of the product, with the risk of non-collection of these co-payments being another cost factor that must be considered by CMS and CAP vendors. Placement of this credit risk on the CAP vendor would place an undue burden upon the vendor and therefore make the program such a high risk that participation may be untenable. We feel that CMS needs to allow the CAP vendor to collect the coinsurance and deductible at the time of pharmacy dispense. In the traditional pharmacy revenue model, a service is performed and revenue is earned based upon the standards set by the state's pharmacy laws for supplying medication to patients. Once the pharmacy has met the lawful definition of "dispense," it has earned its revenue. Services should be billable and payable at the point that the service is performed, both for the physician and the pharmacy vendor. If this cannot be accomplished, CMS needs to otherwise protect the CAP vendor from this potential loss.

Distribution Risk

The risk of loss due to logistical factors makes the potential downside so significant that it prohibits participation in the program. Neither the CAP vendor nor the physician has sufficient financial capacity to absorb losses related to logistical changes. The program needs to address returns in such a fashion that relieves both the CAP vendor and the physician from risk of loss due to factors not within the scope of the services they have successfully provided to Medicare beneficiaries.

Many states do not permit pharmacies to accept returns from patients except under specific circumstances such as when the product is returned in a properly labeled and sealed manufacturer's package or if customized units are individually sealed and part of a closed-drug delivery system.[2] The Food and Drug Administration (FDA) also recommends that pharmacists not accept return of drug products once they have left his or her possession.[3]

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[2] Fla. Admin. Code Ann. r. 64B16-28.118 (2005) (prohibiting returns by patients except for unused portions of a unit dose package dispensed to in-patients in a closed delivery system and if the drug is individually sealed and

The proposed rule suggests that the issue of returns should be addressed between the physician and the pharmacy. However, this may not be feasible under various state pharmacy laws. Such a policy is inconsistent with today's practices and would render the CAP model untenable from a cost-management perspective.

Conclusion

Given that aggregate CAP bids must be submitted at a pricing level under ASP plus six, every burden placed on CAP contractors must be carefully considered. As it stands today, there are significant risks for potential CAP vendors that CMS needs to address in the final rule. Absent any changes to the proposed rule, Priority would most likely not be able to participate as a CAP vendor. Priority appreciates your consideration of these comments and welcomes the opportunity to contribute to the development of a final rule that meets the objectives of Congress and CMS.

Steven D. Cosler
President & Chief Executive Officer

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properly labeled); Md. Regs. Code tit. 10, § 10.34.10.07 (prohibiting returns to a pharmacy's stock of previously sold product unless the product is properly labeled and sealed or, in the case of a unit dose, the pharmacist determines the product to have been handled in a manner that preserves the strength, quality, purity, and identity of the drug).

[3] FDA Compliance Policy Guide § 460.300 (CPG 7132.09).

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APR 26 2005

Specialty Biotech and Distributors Association
1501 K Street
Washington, DC 20005

April 26, 2005

Dr. Mark McClellan
Administrator
Center for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1325-P
200 Independence Avenue, SW
Washington, DC 20201

Re: Competitive Acquisition Program Proposed Rule CMS-1325-P

Dear Dr. McClellan:

The Specialty and Biotech Distributors Association (SBDA), an organization representing specialty distributors that manage the delivery of complex, breakthrough drugs and biologics to physicians and other providers, submits these comments in response to the proposed rule for the competitive acquisition program (CAP) of outpatient drugs and biologicals under Part B ("proposed rule").[1] SBDA applauds the Centers for Medicare and Medicaid Services' (CMS) efforts to implement the CAP program and seeks to work constructively with you to effectuate the policy goals of the Medicare Prescription Drug, Improvement and Modernization Act (MMA) in a manner that best serves the interests of beneficiaries, providers and taxpayers.

I. Summary of Comments

In these comments, SBDA will suggest several modifications to the proposed rule that may increase CAP vendors willingness to participate in the program. The comments will also highlight the structurally significant differences between specialty distributors and specialty pharmacies and recommend policies to ensure that CAP program regulations promote the integrity of products that are distributed throughout the pharmaceutical and biotech supply channel. In light of the structural changes within Part B reflected in this proposal, it will be particularly important for CMS to establish product integrity standards that reflect the "best practices" of the distribution industry in the CAP program. Accordingly, a significant portion of these reply comments will focus on product integrity issues.

The SBDA welcomes the Agency's proposals to enhance compliance with federal law and manufacturers' product specifications. At the same time, we appreciate the fact that CMS has not chosen to create an overly burdensome, and more costly, regulatory regime. Specifically, we applaud the Agency for its recognition that onerous pedigree requirements are impractical

[1] "Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B," 70 Fed. Reg. 10,745–10,773 (Mar. 4, 2005).

and will not enhance product integrity. New pedigree requirements would make this system simply unworkable from both a contractor and a distributor perspective.

As a general matter, SBDA recognizes the great strides that CMS has made in implementing CAP in the proposed rule. We do wish, however, to further refine it in a manner that increases efficiencies for the Program, generates cost savings and maintains product safety. As such, all of the information provided in these reply comments are offered in the spirit of assisting CMS to create a workable delivery system under Medicare Part B.

Because of the complexities involved in the implementation of CAP, SBDA strongly believes that this new system must be phased in slowly in stages in order to maximize the program's likelihood of success. Significant questions have arisen with respect to the control that contractors would actually possess under the proposed rule to manage prescription drug costs and the attendant level of risk that would be borne by the contractors during the three year contract period.

SBDA – an association with several prominent members who may wish to participate in CAP – believes it most effective for the long term success of the program if CMS phased in CAP for one physician specialty over at least a one year period and limited the program to one geographic region until CMS is comfortable that the program will achieve its goals. There simply is not enough experience with this new system yet to implement this program for a significant volume of Part B products. Working with appropriate stakeholders, CMS could utilize a multi-year phase in period to refine the regulatory and statutory aspects of the program that may impede the establishment of a successful system.

With respect to the calculation of vendors' bid prices, SBDA notes that CMS should not include bona fide prompt pay discounts into the contractor's bid submission. Such extension of credit, if undertaken at fair market value and not passed on to the provider, does not constitute a price concession and should not be treated in the same manner as a traditional price discount. In fact, since there is no financial relationship between the contractor and the provider, it would be impossible for the contractor to pass along the prompt pay terms to the provider.

Finally, SBDA believes that the principle of the time value of money, and the risk involved in managing the program, should be appropriately considered when determining how and when CAP contractors may receive payment for product shipped under the CAP program. To address some of these "risk-related" issues, SBDA is submitting an illustrative risk sharing proposal for your consideration. While a number of entities may be attracted by the program's potential, some of the risk to the CAP vendor must be minimized (and the tools provided to manage that risk) in the final rule in order to ensure a sufficient number of bidders with a demonstrated ability to serve the needs of CMS and its constituents. We hope you seriously consider SBDA's proposals.

Of course, risk manifests itself in many ways. Even seemingly small delays in claims processing and payment may lead to great economic costs for CAP contractors and represent a barrier for more wide-spread participation by potential vendors in the CAP program. CAP contractors simply cannot "hold" claims and wait for physicians to submit duplicate claims before they collect monies owed to them. Every day that a contractor must wait to submit a claim represents additional working capital invested by and carrying costs for the CAP vendor and added inefficiencies to the Medicare Program. We see this as a major deficiency in the proposed rule that needs to be addressed.

II. Introduction to the Specialty and Biotech Distributors

Specialty distributors provide tremendous value and efficiencies to the Medicare Program. While often not visible to the public, specialty distributors manage the increasingly complex handling and delivery requirements of drugs and costly new biologics for virtually all of the physician offices in the country. These distributors perform important services such as warehousing products, providing specialty handling and shipping services (such as packaging, refrigeration, or customized dosing), and ensuring the timely delivery of drugs and biologics to physicians and providers. Specialty and biotech therapies are diverse and benefit a wide range of patients including those receiving treatment in the areas of dermatology, gastroenterology, hematology, immunology, infectious disease, pediatrics, neurology, pulmonology, ophthalmology, oncology, and rheumatology.

SBDA is an organization composed of a number of companies interested in maintaining the integrity of the specialty distribution system in physician office and other settings. Members of SBDA include AmerisourceBergen Specialty Group, Cardinal Health, Inc., Health Coalition, Inc., Henry Schein, Inc., Oncology Therapeutics Network and Priority Healthcare Corporation. Together, these organizations represent over 75 percent of the physician office specialty distribution volume in the United States.

III. Explanation of Differences Between Specialty Distribution and Specialty Pharmacy and Discussions Regarding Returns and Licensure Issues

Traditionally, specialty distributors and specialty pharmacies have represented distinct elements of the supply chain. The CAP program appears to blend these roles as it contemplates contractors who will potentially inventory, distribute, and dispense drugs and biologicals. It is instructive, however, to understand the key differences between specialty distributors and specialty pharmacies. Further, it is critical to the success of the bidding process and the CAP program overall for CMS to clearly state whether it intends for vendors to operate under a specialty distributor or specialty pharmacy business model.

In the section on "Bidding Entity Qualifications," CMS notes that a CAP vendor "would be required to maintain an appropriate license in each State in which the drug vendor seeks to operate under the CAP." If the CAP vendors accept and fill patient-specific prescriptions for and dispensing Part B medicines, they would presumably need to be licensed as pharmacies in each state in which they operate as part of the CAP program in order to comply with existing state pharmacy board regulations. However, the CAP rule instead indicates that CAP vendors must be licensed as distributors or wholesalers. Notably, specialty distributors and pharmacies are governed by much different state laws, agencies, regulations and contractual arrangements. As such, CMS appears to be suggesting the creation of a "hybrid" entity that mixes components of the specialty distribution and specialty pharmacy business models.

Unfortunately, the current ambiguity in the proposed rule with respect to these disparate business operating models as well as the complexity and costs of complying with multiple state licensing regimes for both distributors and pharmacies will significantly discourage potential participation by vendors and make day to day operations and compliance with federal and state laws extremely challenging, if not impossible. SBDA strongly urges CMS to make a definitive statement in the Final Rule as to whether the CAP Program will utilize a specialty distribution or

a specialty pharmacy model. To attempt to launch a "hybrid" business model, for which no legal and regulatory precedent exists, will significantly reduce the program's ability to function.

A. Returns

One clear example of the differences between distributors and pharmacies exists in the area of the returns of drug and biological products. Many states do not permit pharmacies to accept returns from patients except under specific circumstances such as when the product is returned in a properly labeled and sealed manufacturer's package or if customized units are individually sealed and part of a closed-drug delivery system.[2] The Food and Drug Administration (FDA) also recommends that pharmacists not accept return of drug products once they have left his or her possession.[3] In contrast, specialty distributors may generally accept product returns under specific circumstances dictated by drug manufacturers. In some circumstances, distributors may be required to accept return of expired product.[4]

The proposed rule suggests that the issue of returns should be addressed between the physician and the CAP vendor. However, there will be no financial relationship between these parties to facilitate an arrangement to address returns. In fact, absent any changes to the proposed rule, physicians will lack any financial incentive to handle product in a manner that adequately protects the CAP vendors interests. CMS may wish to consider providing physicians with a "nominal handling fee" to ensure that returns, claims, copayments and returns are handled in a safe, timely and efficient manner.

CAP vendors simply cannot be financially responsible for the costs of returns. If CMS permits any of this risk shifting to occur from physicians to CAP vendors, this one factor alone will make the program financially untenable. Such a policy is inconsistent with today's practices and would significantly increase the CAP vendor's contract risk. The financial risk in this policy alone is well in excess of the potential profit under an ASP plus six based system.

As discussed above, the return of patient specific scripts is not permitted under state pharmacy laws. Accordingly, leaving the issue of returns to a negotiation between the CAP vendor and the physician is not only financially problematic, but in conflict with state law as well. Clearly, the financial responsibility for returns between the CAP vendor and the physician should be articulated more precisely in the final rule. Here, CMS may look to some existing state laws for suggestions. [5]

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[2] Fla. Admin. Code Ann. r. 64B16-28.118 (2005) (prohibiting returns by patients except for unused portions of a unit dose package dispensed to in-patients in a closed delivery system and if the drug is individually sealed and properly labeled); Md. Regs. Code tit. 10, § 10.34.10.07 (prohibiting returns to a pharmacy's stock of previously sold product unless the product is properly labeled and sealed or, in the case of a unit dose, the pharmacist determines the product to have been handled in a manner that preserves the strength, quality, purity, and identity of the drug).

[3] FDA Compliance Policy Guide § 460.300 (CPG 7132.09).

[4] *See, e.g.*, Ga. Code Ann. § 26-4-115(c) (instructing the Board of Pharmacy to promulgate rules for wholesale distributors that includes a requirement that distributors make adequate provisions for the return of outdated product); Ga. Comp. R. & Regs. r. 480-7-.07 (2004) (requiring wholesale distributors to make adequate provisions for the return of outdated prescription drug product for up to six months after the labeled expiration date).

[5] In Texas, for example, the entity returning the product has a duty to provide a credit to the party that initially bore the cost of the product. Under Section 291.8, "the pharmacy shall reimburse or credit the entity that paid for the drug including the state Medicaid program for an unused drug returned to the pharmacy. The pharmacy shall maintain a record of the credit or reimbursement" (Section 291.8 Return of Prescription Drugs, Texas Pharmacy Rules) Similarly, CMS should ask physicians to credit CAP vendors if they need to return a product.

SBDA does note that state laws on returns frequently do not address the physician office setting environment. Unless standard federal rules are created, many state pharmacy laws and regulations may need to be modified.

There are other issues that CMS may wish to modify on its returns policy. From a specialty distributor perspective, many of the products involved in CAP will require special storage and handling due to their sensitivity to temperature. CAP vendors will, therefore, as a general matter, be unable to accept some of the specialty products back into the supply channel. In addition, when one takes into account that a significant amount of product may be "broken down" from original packaging by the CAP contractor in order to dispense a prescribed unit of dose, it is clear that product integrity would be jeopardized if specialty distributors were asked to accept these "broken down" returns – that is, those that are not in the manufacturers' original, unopened packaging. At a minimum, CMS needs to be clear that broken down returns cannot be recycled back into the supply chain. To do otherwise, would actually violate the clear terms of the statute since the distributor would no longer be able to guarantee that it obtained product directly from the manufacturer.

B. Licensure Issues, Claims Processing and HIPAA

As CMS refines the CAP model in the final rule, it should also note the differences in licensure requirements between distributors and pharmacies. For example, pharmacies are often required to have licensed pharmacists on staff during hours of operation.[6] In general, although distributors may be required to report extensive information about distributor ownership and management, they face far fewer specific staffing requirements than specialty pharmacies.[7] Additionally, a licensed pharmacy may generally interpret, evaluate, and dispense drug and biological products. Specialty distributors, however, manage inventory and ship product based on general drug orders – not a much more detailed, individual prescription. Although specialty distributors may be registered or licensed by the state, they are not licensed to dispense individual prescriptions to patients. If CMS is looking to establish a distribution model for CAP, it will need to consider how distributors will meet the patient-specific and state by state requirements of that program. As such, the establishment of one federal standard for licensure and patient-specific requirements necessary for CAP should be given serious consideration.

Claims processing and adjudication represent other important distinctions between specialty distributors and pharmacies. Pharmacies must have the technical ability to process third-party payer claims, collect co-payments and adjudicate claims on a patient-by-patient basis. In contrast, distributors are not generally equipped to process such patient level claims and do not maintain systems or personnel who are trained to address these issues.

Treatment under HIPAA provisions is another distinguishing characteristic between specialty distributors and pharmacies. In the preamble to the proposed rule, CMS has indicated that CAP vendors would be treated as "covered entities" under HIPAA provisions.[8] In contrast, specialty distributors are considered "business associates" under the HIPAA laws and regulations. Classification as a "covered entity" imposes significant administrative burdens that "business associates" do not necessarily face. If CMS is interested in "converting specialty distributors" into CAP vendors, it must take into account the added financial and operational

[6] *E.g.*, Ga. Code Ann. § 26-4-110.
[7] *See, e.g.*, Fla. Stat. § 499.012 (enumerating requirements for applicants of wholesaler prescription drug permits).
[8] 70 Fed. Reg. 10,745, 10,760 (Mar. 4, 2005).

burdens associated with complying with a different set of HIPAA rules. HIPAA compliance also serves as an example of the uncertainties associated with a "hybrid" business model.

SBDA encourages CMS to consider these and other distinctions between specialty distributors and pharmacies as it implements the CAP program. These differences are important for CMS to understand as it develops policies for CAP contractors who will interact with manufacturers, wholesalers, specialty distributors and physician offices.

IV. Proposals to Address Levels of Risk Borne by CAP Vendors

SBDA supports CMS' efforts to establish an effective CAP system that will reduce Medicare expenditures. Unfortunately, we are concerned that, in its current form, a requisite number of CAP vendors will not participate in the program. Specifically, SBDA members believe that CAP vendors will be unable to assume the level of financial risk imposed upon them in the proposal.

A. Financial Risks Contained Within CAP Proposed Rule

The level of risk involved in this program is unprecedented in the Medicare Program. If the proposed rule does not change, CAP vendors will be responsible for:

1. The claims for products dispensed to physicians that were ultimately denied on medical necessity grounds.
2. The value of any copayments not collected from patients. (As some studies have indicated that copayments may not be collected up to 35 to 50 percent of the time, this risk alone may eliminate any potential for the CAP vendor to break even.)
3. The time value of money before CAP vendors are paid by the government for inventory that has been shipped to physicians.
4. Products that are wasted or spoiled in the delivery or handling process (these costs may not be recovered under the statute, though they still impact the liability of the CAP vendor).
5. The difference between the bid price for a particular product and the reimbursement price (which is based upon the median of all bids submitted to CMS).
6. The cost of returns (if the policy is not clarified in the final rule).

B. Suggested Initiatives and Discussion of Legal Authority

Given these challenges and the limited tools provided to CAP vendors in the proposed rule to manage drug costs, SBDA strongly encourages CMS to take proactive steps to mitigate risks and to increase the program's attractiveness for potential vendors.

To achieve this goal, SBDA recommends several immediate initiatives: 1) establishment of a pre-review process by the Agency to permit vendors and physicians to verify the medical necessity of a claim before a script is filled; 2) creation of risk corridors to limit the financial risk of the CAP vendors; 3) approval of mechanisms to permit the collection of a copayment at the time a product is dispensed to a patient; and 4) other proposals that reimburse the CAP vendor for costs that may be incurred outside of their control.

SBDA is willing to work with CMS to provide the Agency with greater detail on each of these initiatives and the legal authorities supporting these proposals. As a general matter, though, we believe that CMS possesses broad discretion, through its demonstration authority under the Social Security Act, to initiate measures that provide for more efficient and effective methods of providing care for beneficiaries. The relevant statutory cite follows:

> The Secretary of Health and Human Services is authorized, either directly or through grants to public or private agencies, institutions, and organizations or contracts with public or private agencies, institutions, and organizations, to develop and engage in experiments and demonstration projects for the following purposes:
>
> > (A) to determine whether, and if so which, changes in methods of payment or reimbursement (other than those dealt with in section 222(a) of the Social Security Amendments of 1972) for health care and services under health programs established by this chapter, including a change to methods based on negotiated rates, *would have the effect of increasing the efficiency and economy of health services under such programs through the creation of additional incentives to these ends* without adversely affecting the quality of such services. Social Security Act, 42 U.S.C. 1395b-1 (Emphasis added).

SBDA believes that CMS could legally establish all three of these initiatives in order to "increase the economy and efficiency" of the CAP program.

C. An Illustrative Risk Sharing Proposal

We believe that CMS should give serious consideration to all of the aforementioned suggestions. For purposes of this letter, though, we will focus our discussion on the creation of a risk corridor system. SBDA believes that such a system could be modeled after some of the symetrical Part D provisions, where the government and the Part D plans both share in the risk and the benefits of the program.

Under Part D, plans are at full risk for adjusted allowable risk corridor costs if they are within 2.5 percent above or below their target. If plans incurred allowable costs above 102.5 percent of the target until 105 percent of the target, they would receive increased payments from the government of 75 percent of the allowable costs between those thresholds. After costs exceeded 105 percent, the government would reimburse plans for 80 percent of their costs above that threshold amount.

Conversely, if allowable costs were more than 2.5 percent below the target, the Part D plans would share the savings with CMS. Under that circumstance, plans would need to refund 75 percent of the savings to the government if the allowable costs for the plan fell between 97.5 percent of the target amount and 95 percent. Should the allowable costs fall below 95 percent of the bid amount, the plan would then share 80 percent of all dollars that fall below that threshold level.

SBDA references the Part D risk sharing proposal because it believes that a similar approach (with more narrow corridors) could mitigate vendors' potential losses during the first

few years of the program. Potential CAP vendors will be much more likely to participate in the program if they know their losses will be capped at a particular level. As many of the potential CAP bidders have not previously functioned as insurers, this type of initiative may help attract the entities with the requisite experience of managing and delivering specialty products to physician offices. At the same time, if the program works in a manner consistent with CMS' policy goals, the Agency may also benefit from the upsides of the risk corridor system. Since the corridor is symmetrical, both the government and the CAP vendors will share equally in the advantages and disadvantages of CAP. The charts below illustrate how such a system may work under CAP.

Aggregate Allowable Costs That Exceed Target

Allowable Costs Compared to Target	Government Responsibility	CAP Vendor Responsibility
100 – 102 percent of Target	0 percent	100 percent
102 – 104 percent of Target	75 percent	25 percent
Greater than 104 percent of Target	80 percent	20 percent

Aggregate Allowable Costs That Fall Below Target

Allowable Costs Compared to Target	Government Share of Savings	CAP Vendor Share of Savings
100 – 98 percent of Target	0 percent	100 percent
98 – 96 percent of Target	75 percent	25 percent
Lower than 96 percent of Target	80 percent	20 percent

The numbers suggested above are illustrative of how CMS may implement a risk corridor based approach. In the final rule, we urge CMS to adopt a model such as this, with input from interested parties. This risk corridor would remain in place during the entirety of the three year contract period. The thresholds for risk sharing need not replicate this proposal, but they should take into account the significant risk that may be assumed by CAP vendors during the early stages of the program. Such an approach is clearly permitted under the the Agency's demonstration authority. SBDA would welcome the opportunity to work with CMS as it develops such a system.

V. Product Integrity

SBDA commends CMS for its efforts to ensure the integrity of drug and biological products that are furnished through the CAP program. The proposed rule would require CAP vendors to comport with applicable sections of the Federal Food, Drug, and Cosmetic Act, as well as to take appropriate measures "to assure that processing, handling, storage, and shipment

of drugs and biologicals are adequate to maintain product integrity."[9] SBDA supports these requirements and seeks to work with CMS to ensure compliance with federal law and manufacturer's product specifications. Compliance with these fundamental requirements alone will significantly protect the integrity of CAP drug and biological products. However, SBDA cautions against imposing significant new requirements beyond these protections. Doing so may harm the efficiency and effectiveness of the CAP program while offering no improvement in product integrity for Medicare beneficiaries. Given that aggregate CAP bids must be submitted at a pricing level under ASP plus six, every burden placed on CAP contractors must be carefully considered.

Perhaps most important to ensuring product integrity is CMS' proposed rule, based on statutory provisions in the MMA, that CAP vendors shall acquire the drugs and biological products that they distribute from the manufacturer or from a distributor who has acquired the drug directly from the manufacturer.[10] This one requirement significantly protects product integrity under CAP by limiting purchases of drugs from secondary markets.

A. Examples of Practices Used To Ensure Product Integrity for Distributors

SBDA believes that encouraging responsibility and awareness among manufacturers, wholesalers, distributors, and contractors of broader product integrity practices will help avoid the necessity of imposing product-specific integrity requirements for each drug and biological product. However, SBDA emphasizes that, consistent with the proposed rule, all entities within the supply chain should be taking voluntary steps to ensure that all drugs and biologics comply with the manufacturers' storage and handling requirements. As such, SBDA recommends that CMS require all entities in the supply chain, including wholesalers, distributors, and contractors, to maintain a formal compliance program to ensure adherence to the storage and handling requirements for any given drug or biological product. Evidence of such a compliance program should be presented to CMS when a contractor submits its bid. Simply put, "standard operating procedures" (SOPs) and acceptable protocols should be developed by all entities within the supply chain that handle sensitive Part B products. Upon request, SBDA members would be pleased to assist in the development of such "SOPs."

Beyond establishing voluntary compliance programs and SOPs, distributors and wholesalers must provide basic information to states as part of their license approvals. Some of these requirements have helped identify "bad actors" who were more likely to ignore well-respected supply chain protocols. Some of the information distributors and wholesalers frequently provide to states are as follows and were cited in the proposed rule:

- A list of all state licenses, registrations, or permits that authorize the applicant to distribute prescription drugs;
- Criteria and screening procedures used to hire employees that handle drug product;
- The estimated annual dollar volume of prescription drugs and biologics of the distributor;

[9] 70 Fed. Reg. at 10,759.
[10] 70 Fed. Reg. at 10,759.

- A description of every facility/warehouse used for storage or distribution, including descriptions of security and environmental controls;

- A list of all disciplinary actions by state or federal agencies against the applicant, including actions against principals, owners, directors, or officers over the last ten years; and

- The results of a criminal background check on the contractor, its owners, directors, and officers;

SBDA commends CMS for requiring that CAP vendors include this information in their bid.

In addition to the items listed above, SBDA members are also considering additional methods to protect the supply chain and recommend that CMS does so as well. For example, as an alternative to paper pedigrees, CMS may wish to have distributors verify in their invoice, or otherwise verify, that they have met the statutory requirements of purchasing their biotech or pharmaceutical product directly from the manufacturer. Such an invoice could also be forwarded to the contractors to ensure they are also complying with the MMA's statutory obligations of purchasing a Part B drug or biologic either directly from a manufacturer or through a distributor that purchased a product directly from the manufacturer. SBDA would be pleased to work with CMS to develop standard language that may be included in the transmissions that occur between the distributors and the vendors or the vendors and the physicians. For example, this language could include the following straightforward statements:

From the Distributor to the CAP vendor:

> *"Distributor entity" verifies that this product was purchased directly from the manufacturer.*

From the CAP Vendor to the Physician, one of the following, as appropriate:

> *"CAP Vendor" verifies that this product was purchased directly from the manufacturer;*
>
> *"CAP Vendor" stipulates that it possesses a verification form from the distibutor, from which it purchased this product, that it purchased directly from the manufacturer.*

This straightforward policy will allow contractors to easily demonstrate that they are meeting the terms of the statute. SBDA notes, however, that if CMS follows the aforementioned suggestion, it will also need to comport its policy on returns with this verification system. Should returns be permitted from the CAP vendor to the distributor or from the physician to the CAP vendor, the entity receiving the return may be unable to verify where the product was purchased. In those cases, the entity returning the product would need to verify how it obtained the product and that it was comporting with all applicable laws and regulations.

B. Pedigree Requirements

Recently much attention has been focused on the use of pedigree requirements to ensure that counterfeiting and adulteration of prescription drug and biological product is minimized. Because of the specialized nature of the products SBDA members handle, SBDA recognizes how critical it is that drug and biological product be safely and appropriately stored, shipped and handled. Unfortunately, some organizations have suggested using paper pedigrees to track the distribution history of prescription drugs and biologics. Given the enormous investment and burdens of creating a paper pedigree system, even on an interim basis, SBDA and many experts in the pharmaceutical and biotech supply chain agree with CMS that such a system is completely impractical. This is particularly true because paper pedigrees are subject to record-keeping failures and to forgery.[11] We urge CMS to continue avoiding any use of paper pedigrees under CAP or other payment systems.

SBDA encourages the development of technology, such as radio frequency identification (RFID), that would permit tracking of drug and biological product throughout the distribution chain. However, despite the promise of this technology, CMS should also recognize that implementation of this technology represents a long-term solution and is not a "quick fix" solution to the problem of product integrity. In fact, significant obstacles need to be overcome before RFID is fully operational.

Fortunately, Congress assisted CMS in its efforts to effectively track therapeutic products in the Part B supply chain by imposing statutory requirements that restrict the entities from whom CAP contractors may purchase product. The requirements articulated above will help to alleviate some of the immediate need for a tracking system in this setting. They also increase the likelihood that CAP product may be traced back to the manufacturer through only one or two steps in the supply chain and decreases the need for extensive pedigrees to ensure product integrity.

This statutory safeguard will also give CMS greater leeway in determining when RFID may be deployed throughout the supply chain. This leeway is significant because current estimates that RFID technology will be ready for widespread implementation by 2007 understate the time needed to address technical issues and ensure product integrity. In fact, we do not believe that RFID may not be feasible until 2009 with respect to a number of products that may be offered under the CAP program.

Finally, SBDA notes that any pedigree standards should not unduly hinder the supply chain. For example, distributors, particularly those that handle specialized product, must often make intracompany transfers of product to accommodate customer demands. Ensuring timely access to these important products is critical for beneficiaries. Pedigree or tracking requirements for such intracompany transfers would only create inefficiencies and do not enhance product integrity. Accordingly, we urge CMS to finalize the rule without creating any of these new burdens.

C. Experience of CAP Contractors

[11] HHS Task Force on Drug Importation: Report on Prescription Drug Importation (December 2004), at 42.

SBDA also commends CMS' decision to require CAP bidders to have been in the business of furnishing Part B injectable drugs for at least three years to qualify as a CAP vendor.[12] This requirement ensures that CAP vendors have the requisite experience and stability to deliver timely service to physicians and Medicare beneficiaries. This experience will also help to ensure that CAP vendors are capable of furnishing product that meets all of the product integrity standards established in the proposed rule.

SBDA also notes that CMS may wish to consider additional requirements that ensure that CAP vendors demonstrate financial stability. Any bidder awarded a contract needs to possess financial capabilities to support the program's working capital requirements and financing of inventory. This point needs to be expanded upon in the final rule.

VI. Prompt Pay Terms Should Be Excluded from the CAP Bid

SBDA notes that it would be inconsistent for CMS to include the entirety of prompt pay discounts into bids, if the Agency were to remain consistent to its recent interpretations of the Part B Average Sales Price provisions. As part of the proposed rule, CMS will require CAP vendors to submit their "reasonable, net acquisition costs" for obtaining Part B medicines so that CMS may adjust the contract prices in year two and three of the contract.[13] These net acquisition costs represent "[a]ctual acquisition costs [that] are net of all discounts and rebates provided by the vendor's own suppliers."[14] Discounts enumerated by CMS include "volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, rebates, refunds, and other price concessions."[15]

As SBDA has previously raised with the Agency, prompt pay terms are qualitatively different from price concessions. In fact, calling these terms "discounts" is a misnomer because the monies realized are frequently utilized to compensate the distributor for a host of services provided throughout the supply chain. Bona fide prompt pay discounts represent the costs of services provided for managing the delivery of products to the physician offices and expenses incurred by the distributor associated with setting up, monitoring and collecting payments from such accounts, the credit risk associated with each such account, processing costs, risk of loss (whether from damage, spillage or other causes), insurance and security expenses, restocking and handling costs involved in processing returns and the direct costs of sales. Bona fide prompt pay discounts also represent the time value of money.

Further, in recognition of the fact that there is no financial relationship between the CAP vendor and the provider, they should be excluded from a vendor's bid. This view coincides with the position adopted by CMS in a December 9, 2004 letter to SBDA regarding bona fide service fees and the Average Sales Price (ASP) Calculation. In that letter, CMS noted that "[b]ona fide service fees that are paid by a manufacturer to an entity, that represent fair market value for a bona-fide service provided by the entity, and that are not passed on in whole or in part to a client

[12] 70 Fed. Reg. at 10,760.
[13] 70 Fed. Reg. at 10,764.
[14] 70 Fed. Reg. at 10, 765.
[15] Id.

or customer of the entity should not be included in the calculation of ASP, because those fees would not ultimately affect the price realized by the manufacturer."[16]

Under this rationale, prompt pay discounts reflecting the costs of "bona fide services" performed at fair market value should also be excluded from the list of enumerated discounts that determine the "net acquisition costs" of Part B drugs under the CAP program. So long as prompt pay discounts truly represent the time value of money and the fair market value of the distribution services that are provided and they are not passed on to the providers, they do not represent price concessions and should not be included into the CAP vendor's contract terms or ASP. Ultimately, prompt pay discounts do not affect the price "realized by the manufacturer." The conventional use of the term "prompt pay discount" may confuse some into thinking that a price concession is being provided, but that is not the case. Under CAP or ASP, CAP vendors and distributors would be willing to certify that the value of these terms will not be passed on to physicians.

VII. Delays in CAP Contractors' Ability to Bill the Medicare Program:

The importance of the time value of money is also evident in another part of the CAP program. Under the proposed CAP rule, physicians are generally required to bill their claims within 14 calendar days of the date the drug was administered to the beneficiary.[17] CAP vendors would not receive payment for the Part B product, nor be permitted to bill the beneficiary or the beneficiary's third-party insurance for the copayment, until both the vendor claim and physician claim had been reconciled.[18] Even were the system to operate flawlessly, vendors would experience a greater than two month delay in payment between shipment of the drug, physician submission of the drug claim, and carrier reconciliation of the physician and CAP contractor claims. During this delay the CAP vendor would have significant working capital invested in the inventory/receivables. This delay represents a major cash investment for the CAP vendors and significant interest costs to finance.

This situation is further exacerbated with respect to the collection of beneficiary copayments. Every day that transpires without collecting a copayment significantly impairs its collectability and the vendor's ability to recover the investment it made in the product. With at least twenty percent of CAP vendors' revenue coming from Medicare beneficiaries' copayments, this is a significant, possibly an insurmountable concern, especially in light of the ceiling imposed on CAP bids. This risk alone may prevent some potential vendors from submitting bids.

SBDA also notes that few mechanisms exist within the proposed rule to encourage physicians to submit their claims on a timely basis. Absent providing the contractors with some new mechanism or enforcement tool, it is quite likely that their ability to eventually realize all of the claims owed to them will be reduced. Accordingly, SBDA encourages CMS to adopt partial payment of the CAP vendor's claim upon shipment of the product. This would reduce the financial harm experienced by the vendor from physician claim submission delays and at least

[16] December 9, 2004 Letter from Herb B. Kuhn, Director, Center for Medicare Management to John Gray, President and CEO, Healthcare Distribution Management Association and Steve Collis, President, Specialty Biotech and Distributors Association.
[17] 70 Fed. Reg. at 10,755.
[18] 70 Fed. Reg. at 10,756.

attempt to account for the time value of the funds committed by the CAP vendors in the form of product shipped to physicians.

This provision appears especially equitable because the risk of non-payment when the physician fails to file a claim rests on the CAP vendor, who must expend time and resources to informally encourage the physician to file the appropriate claim or engage in the dispute resolution provisions proposed by CMS.[19] Hopefully, the potential threat of suspension of a physician's CAP participation agreement should motivate physicians to submit their CAP claims in a timely manner.[20] However, intermediate steps may also be required. We note that some type of enforcement is important in the event that informal processes fail to encourage timely filing of physician claims. SBDA commends CMS for developing policies that will ensure the financial integrity of all participants in the CAP program.

VIII. Timely Shipment of CAP Product

SBDA supports CMS' efforts to ensure timely delivery of CAP drugs and biological products. The routine shipment of CAP products should occur within a one to two business day period. CAP vendors, though, should not be under a mandate to provide emergency drug orders the next day for orders received beyond 3:00 p.m. the previous day (vendor's local time).[21] Rather, CAP vendors should exercise best efforts to ensure next day delivery of emergency orders. In some cases, it is not feasible to guarantee next day service of product that must be specially prepared or shipped to remote areas, when the order is received after 3:00 p.m. the previous day. It is important to note that all shipping costs are paid by the CAP vendor.

IX. Conclusion

SBDA appreciates your consideration of these positions and welcomes the opportunity to meaningfully contribute to the development of the final rule.

***

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[19] 70 Fed. Reg. at 10,758.
[20] 70 Fed. Reg. at 10,758.
[21] 70 Fed. Reg. at 10,760.

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April 26, 2005

The Honorable Mark B. McClellan, M.D., Ph.D.
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Re: Comments on Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals under Part B, 70 Fed. Reg. 10,746 (March 4, 2005) [CMS-1325-P]

Dear Dr. McClellan:

AstraZeneca (encompassing AstraZeneca Pharmaceuticals LP and AstraZeneca LP) ("AstraZeneca") is pleased to submit comments on the proposed rule issued by the Centers for Medicare & Medicaid Services ("CMS") to implement the Competitive Acquisition of Outpatient Drugs and Biologicals under Part B (the "Proposed Rule"), 70 Fed. Reg. 10,746 (Mar. 4, 2005). We appreciate this opportunity to share our views on this important component of the reforms included in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA").

AstraZeneca is one of the world's leading pharmaceutical companies, engaged in the research and development of new medicines. Through its leadership in the cardiovascular, oncology, neuroscience, gastrointestinal, and respiratory areas, AstraZeneca is committed to the discovery of drugs that will allow Medicare beneficiaries to lead longer, healthier, and more productive lives. In keeping with this commitment, AstraZeneca manufactures several drugs that are reimbursed under Medicare Part B and will be included in the Competitive Acquisition Program ("CAP"). We support the development and implementation of the CAP in a manner that provides open access to drug therapies, ensures continuity of patient care, and includes only Food and Drug Administration ("FDA") approved safe and effective medications.

CMS can provide open access to drugs under the CAP by ensuring that physicians, not CAP vendors, are responsible for clinical decision-making. The role of CAP vendors will be to ensure that physicians have timely access to drugs required by their patients through the procurement and distribution of drug products and management of Medicare and beneficiary reimbursement. The final regulations should explicitly provide that CAP vendors are prohibited from establishing formularies, which likely would restrict or otherwise influence prescribing decisions. If physicians cannot receive most medically-appropriate drugs through the CAP, or are required to go through a cumbersome process to obtain needed drugs outside of the CAP framework, it will undermine incentives for physicians to participate in the CAP and jeopardize the success of the program.

CMS also must ensure that the new CAP does not disrupt Medicare beneficiaries' ongoing or emergent medical treatments. Medicare beneficiaries often experience multiple medical conditions, and medication regimens must be carefully developed and adjusted to address possible adverse drug interactions and to maximize health benefits to patients. The CAP should be implemented in a manner that does not force beneficiaries to change successful medication therapies due to the establishment of narrow drug categories and burdensome administrative hurdles to obtain drugs outside of the CAP.

In order to ensure the safety and efficacy of prescription drugs provided to Medicare beneficiaries, CMS should explicitly state in the final rule that only drugs approved by the FDA will be covered and reimbursed under the CAP. As discussed below, this would prohibit CAP vendors from substituting cheaper but untested products, such as certain pharmacy compounded solutions or illegally imported products, for FDA-approved products. Such safeguards are necessary to protect Medicare beneficiaries from potentially ineffective or even dangerous medications.

The following comments address a number of specific program design considerations raised in the Proposed Rule. We are available to provide additional information about any of these items or answer any questions you may have.

I. CATEGORIES OF DRUGS TO BE INCLUDED UNDER THE CAP

A. Competitively-Biddable Drugs

The MMA defines the term "competitively biddable drugs and biologicals" for purposes of the CAP as "a drug or biological described in section 1842(o)(1)(C) of the Act and furnished on or after January 1, 2006." Such drugs include most drugs paid under Medicare Part B and not otherwise paid under cost-based or prospective payment systems, with certain statutory exceptions. As CMS points out, the statutory definition of "competitively biddable drugs" includes: drugs administered incident to a physician's service; drugs administered through durable medical equipment ("DME"), with the exception of DME infusion drugs; and some drugs usually dispensed by pharmacies (e.g., oral immunosuppressive drugs). However, CMS is proposing to include in the CAP only Part B drugs that are furnished "incident to" a physician's service because certain operational aspects of the CAP (e.g., physicians elect to participate in the CAP, payment for CAP drugs) is conditioned upon physician drug administration. CMS solicited comments on its proposed limitation of CAP to Part B drugs furnished "incident to" a physician's service.

First, AstraZeneca supports CMS's proposal to limit the CAP initially to drugs furnished incident to a physician's service. We believe that such a limitation in the early stage of the CAP would simplify distribution mechanisms, education and outreach efforts, and other administrative issues as the new program is implemented and operational issues are refined.

Because the statute specifically includes certain other Part B drugs in the CAP, however, CMS should consider expanding the CAP in the future to include DME-administered drugs, such as respiratory products, and other statutorily-referenced drugs. Additional Part B suppliers, including small DME companies, would be able to take advantage of the administrative simplifications offered by the CAP, including the opportunity not to collect beneficiary copayments or negotiate individual drug purchases. We recognize that including expanded categories of drugs would necessitate that CMS consider certain operational changes, such as permitting suppliers and pharmacies to elect to contract with CAP vendors. Including suppliers and pharmacies in the CAP would be consistent with CMS's

goal to provide opportunities for those who do not wish to be in the business of drug acquisition and would ensure that physicians, and not vendors, suppliers, and/or pharmacists, would be responsible for clinical decision-making. We therefore recommend that CMS consider as the CAP is being implemented what refinements would be necessary to expand CAP coverage to additional categories of drugs.

Second, AstraZeneca recommends that CMS explicitly state in the final rule that, regardless of which categories of drugs are covered by the CAP, Medicare drug coverage under the CAP is limited to drugs that have been approved by the FDA, consistent with Social Security Act § 1861(t). This would help ensure the safety and efficacy of drugs furnished to Medicare beneficiaries under the CAP and discourage CAP vendors from substituting cheaper but untested products, such as certain pharmacy compounded drugs, for FDA-approved products. For instance, Medicare covers AstraZeneca's Pulmicort Respules®, the only FDA-approved inhaled corticosteroid for nebulization, under HCPCS code J7626. We are aware that Medicare currently is reimbursing (perhaps unknowingly) pharmacy compounded budesonide inhalation solutions when these drugs are billed using HCPCS code J7626. These compounded solutions are not FDA-approved generic equivalents of Pulmicort Respules®, are not proven to be clinically equivalent for safety and efficacy to Pulmicort Respules®, and are not guaranteed to be manufactured in a sterile environment in compliance with FDA regulatory requirements. In fact, as evidence by recent FDA enforcement actions, the FDA considers these copycat versions to be unapproved new drugs that violate the Food, Drug and Cosmetic Act. Thus, CMS must protect Medicare beneficiaries from potentially ineffective, or even dangerous, medications by limiting CAP drugs to those that are FDA-approved.

B. Phase-In by Drug Category

AstraZeneca supports phasing in the CAP by beginning with those drugs typically administered by oncologists. The inclusion of a subset of Part B drugs should allow for more streamlined, effective management of the CAP during its first year. Because oncology drugs represent a large portion of Medicare Part B drugs furnished incident to a physician's service, we believe they are good candidates for initial inclusion in the CAP. Moreover, including drugs administered by a significant number of physicians is likely to give CMS meaningful data and experience to address implementation and operational issues before the CAP is made more widely available. AstraZeneca also is aware that physicians who typically administer oncology drugs tend to be very experienced with Medicare drug reimbursement. This may enhance CAP participation because these physicians will be in a better position to make an informed decision concerning the CAP and may highly value the ability to choose an alternative to the current average sales price ("ASP") based "buy and bill" system.

AstraZeneca further supports CMS's proposal to not strictly limit the CAP phase-in to a single physician specialty but, instead, to allow any physician who furnishes such CAP covered drugs to participate. Specifically, AstraZeneca endorses the following CMS discussion in the regulatory text to the Proposed Rule:

> It is important to note that, if we choose to phase in the CAP by restricting the program initially to drugs typically administered by members of one specialty, all physicians who administer the drugs selected would still be eligible to elect to obtain these drugs through the CAP and to select a vendor of these drugs. For example, if we choose to phase in the program initially with drugs typically administered by oncologists, participation in the CAP would not be restricted to

oncologists; non-oncologists who prescribe these drugs would still be eligible to elect the CAP and to select a vendor from which to obtain these drugs.

70 Fed. Reg. 10,750 (emphasis added).

AstraZeneca requests that CMS include this provision in the final rule and grant physicians open access to the CAP. We believe such an approach recognizes the complexities of medical practices and that certain drugs typically may be administered by more than one physician specialty. For example, although the class of LHRH agonists is used to treat prostate cancer, these drugs are most commonly administered in the physician office setting by urologists, not oncologists. CMS's continued flexibility in implementing the CAP will encourage physician participation and help ensure the long-term success of the CAP.

C. Provision of Drugs Within a HCPCS Code

Under the Proposed Rule, a potential CAP contractor would be required to bid on all HCPCS codes included within a drug category. However, CMS is proposing that a CAP vendor would not be required to provide every National Drug Code ("NDC") associated with a HCPCS code. If a vendor does not contract to furnish a drug or particular formulation of a drug, the physician would obtain and be reimbursed for the product under the ASP system if the drug is "medically necessary." In such cases, the physician would be instructed to place a "furnish as written" modifier on his or her claim form and bill his or her Medicare carrier for the drug and the administration fee. CMS anticipates that the physician's carrier would, at times, conduct a post payment review of the use of the "furnish as written" modifier. If the carrier determined that the physician had not complied with furnish as written requirements and that a specific NDC or brand name drug was not medically necessary, the carrier could deny the claim for the drug and the administration fee.

AstraZeneca believes that physicians, not CAP vendors, should make prescribing decisions. We therefore recommend that CAP vendors be required to provide all available FDA-approved drugs within a HCPCS code. AstraZeneca has concerns about giving a CAP vendor discretion to choose which individual drugs within a HCPCS code the vendor may choose to provide. First, this would essentially establish a formulary without providing any of the beneficiary safeguards CMS has established for Part D drug plans that use formularies (e.g., the creation of a pharmaceutical and therapeutic committee that includes practicing physicians and/or pharmacists, formulary decisions must be based on scientific data and standards of practice, etc.). Second, this proposal is inconsistent with CMS's well-established position that a HCPCS code represents a category of similar products and not specific products. Permitting CAP vendors to provide only one NDC within a HCPCS code does not recognize that products within a HCPCS code are not equivalent, and patients can have varied responses to different products, strengths, routes of administration, mechanisms of action, and formulations that may be included within the same HCPCS code. CAP vendors should not be permitted to restrict physicians' choices of the most medically appropriate products. Third, while CMS states that physicians would be able to obtain drugs outside of the CAP if medically necessary, this raises administrative hurdles for physicians and could result in either (1) physicians choosing less medically appropriate drugs in order to avoid "buying and billing," or (2) physicians choosing not to participate in the CAP so that their medical choices are not compromised. Finally, this proposal could jeopardize continuity of care for beneficiaries and undermine treatment options.

II. CAP BIDDING PROCESS - EVALUATION AND SELECTION: INCLUSION OF CAP IN ASP CALCULATIONS

A. Average Sales Prices Used to Evaluate CAP Bids

AstraZeneca requests that CMS clarify in the final rule that, for purposes of determining whether a CAP bid price exceeds ASP+6%, it will use a 12-month rolling average. The Proposed Rule provides that bid prices submitted by potential CAP vendors may not exceed the payment level under the ASP payment methodology. However, the time period that CMS will consider in making its determination is not specified. AstraZeneca supports using a 12-month rolling average to account for fluctuations in ASPs from quarter-to-quarter and give CMS a more objective basis to evaluate bid prices. CMS's reliance on ASPs drawn from only one quarter potentially could cause CMS to select a CAP vendor that has submitted bid prices that generally exceed ASP+6% but are below ASP+6% for the quarter being used as a reference point. Such a result would be inconsistent with the purpose of the ASP+6% provision and would compromise the ability of the CAP to realize savings to the Medicare program.

AstraZeneca supports CMS's proposal to update CAP payment amounts on an annual basis based, in part, on the payment rates under the ASP methodology. We request that CMS clarify that, for purposes of performing its annual update, CMS also will use a 12-month rolling average ASP.

B. Inclusion of Manufacturer Prices Under the CAP in the Calculation of Average Sales Prices

AstraZeneca supports the inclusion of manufacturer prices made available under the CAP in the calculation of ASP as it relates to Medicare Part B and requests that CMS provide guidance on this issue in the final rule.[1] Over the past year, CMS and manufacturers have been evaluating whether CAP prices should be included in ASP. Upon additional review, and based on the definition of ASP in the MMA, we believe manufacturer prices offered under the CAP must be included in ASP calculations. We note that the definition of ASP in the MMA contains very few exceptions to the calculation methodology and prices offered under the CAP are not among them. Further, CMS's exclusion of manufacturer prices offered under the CAP from the calculation of ASP would be inconsistent with CMS's current ASP calculation methodology.

C. "Fee-for-Service" Arrangements between CAP Vendors and Manufacturers

AstraZeneca requests that CMS provide guidance in the final rule concerning the types of services, if any, that CAP vendors would be permitted to provide manufacturers in exchange for service fees. If CMS determines that such fees are permissible, AstraZeneca requests that CMS include strong safeguards in the final rule to protect against CAP vendors trying to influence product utilization based

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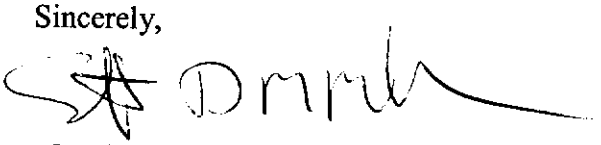
1 To be clear, our comments do not address the treatment of CAP prices in the calculation of ASP as related to other federal or state programs (e.g., Medicaid, Medicare Part D, or state rebate requirements).

on vendors' ability to negotiate fee-for-service arrangements with manufacturers. AstraZeneca also requests that CMS clarify the treatment of service fees for purposes of calculating ASPs. It would be most consistent for CMS to apply the same criteria applicable to the treatment of service fees in traditional "buy and bill" transactions to the treatment of service fees for purposes of the CAP. This would require manufacturers to include service fees in the calculation of ASP if they ultimately affect the price actually realized by the CAP vendor.

* * * * *

Again, AstraZeneca appreciates the opportunity to comment on the CAP. We look forward to working with CMS on the implementation of the CAP to promote high-quality care for Medicare beneficiaries while improving the administration of the Medicare program. Please do not hesitate to contact me at 202.350.5577 or by electronic mail at Stephen.S.D.McMillan@AstraZeneca.com if you have any questions or need further information about these comments.

Sincerely,



Stephen McMillan
Director, Government Reimbursement

JEFFERSON - BLOUNT - ST. CLAIR
MENTAL HEALTH / MENTAL RETARDATION AUTHORITY
940 Montclair Road Suite 200 Birmingham, Alabama 35213 www.jbsmha.com
Telephone: (205) 595-4555 Voice Mail: (205) 380-6460 Fax: (205) 592-3539 TDD: 1-800-545-1833 ext. 516

April 25, 2005

Center for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

As Medical Director of the Jefferson-Blount-St. Clair Mental Health Authority, I am writing of my concerns about the proposed rule: Competitive Acquisition Program (CMS-1325-P). My agency serves the Seriously Mentally Ill (SMI) citizens of our community. Many of these SMI citizens are unable/unwilling to comply with daily oral medication regimens. For many SMI individuals, their illness destroys their insight into their condition – causing them to decline oral medications on a daily basis. For others who realize their need for daily medicines, compliance is complicated by many factors, including; homelessness, substance abuse, socioeconomic limitations, and the presence of limited support persons.

For our most vulnerable citizens (the SMI) to remain safe and stable, long-term injectable antipsychotics are essential. With the implementation of the Medicare prescription benefit in January, 2006 – these injectable medications will be all but impossible to obtain by SMI individuals with Medicare only (or for those who have dual eligibility for Medicare Plus Medicaid QMB).

Interestingly, I would predict that net Medicare costs would increase if the proposed Competitive Acquisition Program be implemented as planned. The cause would likely be increased inpatient hospital expenses from medication non-compliant SMI persons. As a representative on the JBSMHA and an active Board Member for NAMI – Alabama, I request that the proposed rule be changed to include the psychiatric drugs in the CAP program.

Sincerely Yours,

James E. Parker, M.D., F.A.P.A.
Medical Director

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APR 26

LifeSpring

Administration
460 Spring Street
Jeffersonville, IN 47130
(812) 280-2080

Adult Behavioral Health Svcs
460 Spring Street
Jeffersonville, IN 47130
(812) 280-2080

Child & Family Services
460 Spring Street
Jeffersonville, IN 47130
(812) 280-2080

Dual Diagnosis Center
1401 Mitchell Avenue
Jeffersonville, IN 47130
(812) 283-6606

Turning Point Center
1060 Sharon Drive
Jeffersonville, IN 47130
(812) 283-7116

Floyd County Office
824 University Woods Drive
Suite 6-10
New Albany, IN 47150
(812) 981-2594

Harrison County Office
535 Country Club Road
Corydon, IN 47112
(812) 738-2114

Jefferson County Office
606 East Main Street
Madison, IN 47250
(812) 262-4513

Scott County Office
75 North 1st Street
Scottsburg, IN 47170
(812) 752-2837

Washington County Office
1321 Jackson Street
Salem, IN 47167
(812) 883-3095

Indicates return address

April 20, 2005

Center for Medicare & Medicaid Services
Department of Health & Human Services
P.O. Box 8010
Baltimore, MD 21244-8010

Attn: CMS-1325P

To Whom It May Concern:

The Medication Modernization Act (MMA) that created a new system for physician to obtain drugs currently covered under Medicare part B benefit has posed problems in the treatment of our patients. This "buy and bill" system for obtaining Part B covered drugs is hampering the provider's ability to access some therapeutic options, particularly in the area of mental health care.

The Medical Staff of LifeSpring; a Community Mental Health Center would like to express concerns/issues regarding the Medicare Competitive Acquisition program (CAP) proposed rule. It is of the utmost importance that there is an inclusion of psychiatric drugs with no exclusion based on cost savings. It is important that the Center for Medicare and Medicaid Services (CMS) include psychiatric drugs in the initial stages of CAP to alleviate barriers to access inherent in the current system. Since CMS has yet to define the categories of Part B drugs, it is important that CMS create a category that includes mental health drugs, including the long-acting injectable antipsychotics. Since CMS has yet to define the reimbursement process for vendors, it is important for CMS to address how vendors should handle uncollectible co pays and other reimbursement issues that would threaten therapy persistency. Often times, when there are barriers to patients accessing appropriate/necessary medication/treatment, it results in the patient requiring hospitalization. This is definitely not cost effective.

It is our utmost concern that our patients continue to have access to the medication/treatments necessary for their well being.

Joy McAffee MD
Staff Psychiatrist

Mary C. Brandis M.D

Wanda Barker BSN V.P. nursing

L. Howard M.D

Leah Q Dillemuth

MICHAEL G. BRESLIN
COUNTY EXECUTIVE

ALBANY COUNTY
DEPARTMENT OF MENTAL HEALTH
175 GREEN STREET
ALBANY, NEW YORK 12202
TREATMENT SERVICES (518) 447-4555
ADMINISTRATIVE SERVICES (518) 447-4537
FAX (518) 447-4577

ROBIN B. SIEGAL, Ph.D.
EXECUTIVE DIRECTOR

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APR 26

April 13, 2005

To Whom It May Concern:

I am writing in regards to the Medicare Competitive Acquisition Program for Part B Drugs. It is very important clinically as well as fiscally that psychiatric patients on Medicare have access to their mediations including long-acting injectible antipsychotic medications. As it now stands, many of our patients are not able to acquire the psychiatric medications they need resulting in worsening of their symptoms and preventable serious consequences including suicide, violent acts, and expensive hospitalizations. For example, Mr. C, a gentleman who suffers from Bipolar I Disorder, has not been able to obtain Risperdal Consta and instead is treated with an older, less effective antipsychotic. Despite compliance with his injections he developed a manic episode with agitation and delusions. He became violent necessitating hospitalization for two months. Such lengthy, expensive treatment could be prevented in the near future with the inclusion of psychiatric medications in the initial phase of the Competitive Acquisition Program.

Sincerely,

Dr. David Pallas

Dr. Marcos Nieves

Dr. Anthony Ferraioli

Dr. Emilio Ruelos

APR 26 2005

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MASSACHUSETTS GENERAL HOSPITAL

HARVARD MEDICAL SCHOOL

Medical Director
Freedom Trail Clinic
Erich Lindemann Mental Health Center
25 Staniford Street
Boston, Massachusetts 02114
Tel: 617.912.7899, Fax: 617.742.1305
E-mail: dgoff1@partners.org

Donald C. Goff, M.D.
Associate Professor of Psychiatry

April 21, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1325-P
PO Box 8010
Baltimore, MD 21244-8010

Dear Members of the CMS Panel Reviewing CAP:

As Director of the Schizophrenia Program of the Massachusetts General Hospital, I am writing in support of the inclusion of psychiatric drugs in the Competitive Acquisition Program (CAP). This is of particular importance for long-acting injectable antipsychotic medications. Long-acting antipsychotic medications are critically important for the treatment of a substantial number of schizophrenia patients who do not reliably take oral medication and are at risk for relapse and rehospitalization without this treatment option. Without inclusion in the CAP, psychiatric patients will face serious barriers to obtaining this important class of medication.

Thank you for your consideration of this recommendation.

Sincerely,

Donald Goff, MD
Director,
MGH Schizophrenia Program

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APR 26 2005

UMKC
SCHOOL OF MEDICINE

Stuart Munro, M.D.
Chair, Department of Psychiatry
School of Medicine
University of Missouri-Kansas City

1000 E 24th Street
Kansas City, Missouri 64108
816 512-7417
FAX 816 512-7440
stuart.munro@dmh.mo.gov

April 26, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1325-P
PO Box 8010
Baltimore, MD 21244-8010

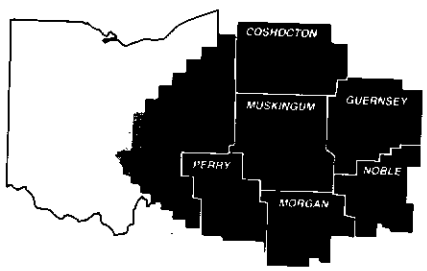
To whom it may concern:
I am writing to express my support for the inclusion of psychiatric medications in Phase I of the Medicare Competitive Acquisition Program for Part B Drugs. I have reviewed the program as described in the Federal Register of March 4, 2005 and feel that inclusion of psychiatric medications as soon as possible will be of great benefit to the patients we serve through the Department of Psychiatry at the University of Missouri-Kansas City School of Medicine. Continuity of care and access to vital medications will be enhanced at our primary clinical sites, namely, Western Missouri Mental Health Center and Truman Medical Center Behavioral Health Network by inclusion of psychiatric medications at the earliest stage (January 1, 2006).

I also feel that it would be important that CMS create a category of Part B drugs that includes mental health drugs, including long-acting injectable antipsychotic medication.

I would like to thank-you for your kind attention to my comments.

Sincerely,

Stuart Munro, MD
Chair



Six County, Inc.

A private, behavioral health care corporation

A CONTRACT PROVIDER FOR MENTAL HEALTH AND RECOVERY SERVICES BOARD

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APR 26 2005

Administrative Office
2845 Bell Street
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701 Main Street
Coshocton OH 43812-1615
740/622-3404
Fax: 740/622-3412

Guernsey Counseling Center
2500 John Glenn Highway
Cambridge OH 43725-9028
740/439-4428
Fax: 740/439-3389

Morgan Counseling Center
915 S Riverside Drive
P O Box 506
McConnelsville OH 43756-0506
740/962-5204
Fax: 740/962-3688

Muskingum Counseling Center
2845 Bell Street
Zanesville OH 43701-1794
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Fax: 740/588-6204

Noble Counseling Center
44020 St Rt 821
Caldwell OH 43724-9124
740/732-5233
Fax: 740/732-4777

Perry Counseling Center
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New Lexington OH 43764-9511
740/342-5154
Fax: 740/342-5155

C.O.R.E. Enterprises
1280 Linden Avenue
Zanesville OH 43701-2969
740/452-7477
Fax: 740/455-4139

Residential Crisis Stabilization Unit
3405 Dillon Acres Drive
Zanesville OH 43701-9658
740/455-4132
Fax: 740/455-5322

CRISIS HOTLINE
In Muskingum County
740/453-5818
Other Counties
1-800/344-5818

WEBSITE
www.sixcounty.org

April 22, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention CMS-1325-P
P.O. Box 8010
Baltimore, MD 21244-8010

RE: Request to Include All Mental Health Therapies in Phase 1 of Competitive Acquisition Program (CAP)

To Whom It May Concern:

Six County, Inc. is a private, not-for-profit, 501©(3) community behavioral healthcare corporation in Ohio. Six County, Inc. began operations in 1969 to provide community mental health and psychiatric services to the residents of six rural southeastern Ohio Appalachian counties. These six counties are: Coshocton, Guernsey, Morgan, Muskingum, Noble and Perry. Six County, Inc. employs psychiatrists, physicians, and a certified psychiatric nurse practitioner to evaluate, prescribe and monitor psychiatric medications to children, adults and older adults who are diagnosed with a mental or emotional disability.

Six County, Inc. strongly requests that the Centers for Medicare and Medicaid Services include **all** psychiatric mediations in Phase 1 in the Competitive Acquisition Program (CAP) to alleviate barriers inherent in the current system and to enhance access to new injectable psychiatric medications, especially the long-acting injectable antipsychotic medications, for Medicare eligible patients. It is very important that the Centers for Medicare and Medicaid Services create a category under Part B that includes psychiatric drugs including long acting injectable antipsychotic medications. These inclusions would simplify, streamline and make more efficient the access to these psychiatric medications to Medicare eligible patients as well as the billing and payment for these medications themselves, especially for the new injectable long-acting antipsychotic medications. We would also strongly urge the Centers for Medicare and Medicaid Services, in finalizing the reimbursement processes to the selected specialty pharmacy provider vendors, that the final reimbursement processes include how vendors are to address uncollectible co-pays and any other reimbursement issues that would threaten therapy persistency.

Six County, Inc. believes that, if the above requested inclusions are made in the finalization of the CAP, this will improve and increase access to the new injectable long-acting antipsychotic medications and will shift the reimbursement process for the medication from the mental health services provider to the specialty pharmacy provider

vendor, where it should be. For one new injectable long-acting antipsychotic medication, the current process is dramatically different than for all other psychiatric medications, injectable and oral, that our physicians and psychiatrists prescribe and nurse administer by injection. For this one new injectable antipsychotic medication, the current process is the exception in comparison to all other psychiatric medications we prescribe and/or administer. The current process for this one injectable medication is time consuming and burdensome for the professional nursing and support staff and the Medicare patient, and causes additional costs in staff time as well as cash flow problems for the non-profit (and budget tight) mental health service provider. This new injectable antipsychotic medication is very costly.

The current process for this one new injectable antipsychotic medication first involves the nursing staff completing, with the Medicare patient, a benefits verification form that the nurse then submits to a patient benefits verification provider. We have to await that provider's verification of the patient's insurance coverage for the purchase of the medication, e.g. Medicare, Medicaid, insurance or no coverage. Once the benefits verification provider verifies to our nursing staff the coverage the patient currently has for the purchase of the medication, our nursing staff can then order the medication from the medication distributor who then ships the injectable medication to us, the service provider. When the medication is ordered, the medication distributor bills the service provider for the medication, and we, the service provider, have to pay for the medication within 30 days of receipt of the bill. However, when the injection is given to the patient is when we, the service provider, can bill Medicare for the medication itself. There is a gap from the time the medication distributor bills us and we have to pay the distributor for the medication, and the billing to and receipt of reimbursement from Medicare or Medicaid for the medication itself. This then results in a cash flow problem for the non-profit (and budget tight) service provider. For almost all of the patients on this injectable antipsychotic medication, they receive an injection every two weeks. As more patients are prescribed this new injectable antipsychotic medication, there is a significant increase in the potential for a <u>significant</u> cash flow problem to occur for the service provider. This one new injectable antipsychotic medication is proving quite beneficial for our Medicare and Medicaid patients who are now on this medication. This new injectable medication required that we, the service provider, set up new billing codes for the billing of the medication itself to Medicare, Medicaid and the patient for their co-pay, as well as new vendor codes for payment for the medication to the medication distributor. We have never had to order and purchase any other injectable or oral psychiatric medication. This entire process caused confusion for patients and staff and causes additional costs in staff time, i.e., nursing, support and billing staff.

In contrast to the above described process for this new injectable antipsychotic medication, for <u>all other</u> injectable psychiatric medications, our physicians and psychiatrists issue a prescription that the Medicare or Medicaid patient takes to their pharmacy which then dispenses the medication by vile to the patient. The patient brings the vile with them to their appointment with our physician or psychiatrist. The injection is then given by one of our psychiatric nurses and we retain the medication as patients are usually on a bi-weekly schedule for their injection. We then bill Medicare or Medicaid for the <u>injection only</u> and have **<u>no</u>** involvement in the ordering, payment to a distributor, and then billing and awaiting payment for the medication itself. This system for all other injectable psychiatric medications that are obtained by the Medicare patient at his/her pharmacy is a superiorly more efficient and consistent system for the patient and the

mental health service provider, as this has been the long standing process to obtain all medications whether orally or injectable.

Six County, Inc. understands that the above described process for this one new injectable long-acting antipsychotic medication will be the same process for other new injectable long-acting antipsychotic medications that come on the market in the future **unless** the above requested Inclusions are made into Phase 1 of the CAP.

Six County, Inc. appreciates the Centers for Medicare and Medicaid Services consideration of our request for the above specified inclusions in the Competitive Acquisition Program.

Sincerely,

Robert R. Santos

Robert R. Santos, ACSW, LISW
Executive Vice President & Chief Operating Officer

Cc: Senator Mike DeWine
140 Russell Senate Office Building
Washington, D.C. 20510

Senator George Voinovich
524 Hart Senate Office Building
Washington, D.C. 20510

Representative Robert Ney
2438 Rayburn House Office Building
Washington, D.C. 20515-3518

1520 Kensington RD Suite 202
Oak Brook, Illinois 60523
630/573-0600 / FAX 630/573-0691
E-mail: info@asge.org
Internet: www.askasge.org

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April 26, 2005

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1325-P
Room 445-G
200 Independence Ave, SW
Washington, DC 20201

Re: Competitive Acquisition of Outpatient Drugs and Biologicals under Part B, Proposed Rule

Dear Doctor McClellan:

The American Society of Gastrointestinal Endoscopy (ASGE) appreciates the opportunity to comment on this proposed rule for the Competitive Acquisition Program (CAP).

ASGE welcomes the option that the CAP offers to physicians in the provision of drugs to Medicare beneficiaries. However, we have a number of concerns with the CAP as outlined in the proposed rule. These include the following:

- The impact that the sales to vendors might have on the future calculation of the average sales price for determining payment under 106% of ASP for physicians who do not participate in the CAP.
- The need to assure that new drugs that may not have been on the market when vendors developed their bids are covered under the CAP program.
- The need for CMS to find ways to reduce the added administrative burden on physicians including establishing an administrative service fee to cover the added costs of participating in the CAP.

We have reviewed the comments submitted by the American Gastroenterological Association (AGA) and are fully in agreement with AGA's positions. Therefore, rather than submit an identical set of detailed comments and recommendations, ASGE would like to go on record as endorsing the comments submitted by AGA. A copy of these comments is enclosed.

Thank you for our consideration.

Sincerely yours,

Maurits Wiersema, MD

Maurits Wiersema, MD
Chairman, Practice Management Committee

APR 26 2005

genzyme
GOVERNMENT RELATIONS

GENZYME CORPORATION
1020 NINETEENTH STREET, N.W.
SUITE 550
WASHINGTON, D.C. 20036
202-296-3280
FAX 202-296-3411

April 26, 2005

BY HAND DELIVERY

Dr. Mark McClellan, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: CMS-1325-P (Medicare Program: Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B)

Dear Dr. McClellan:

Genzyme Corporation ("Genzyme") is pleased to have the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) proposed rule regarding the competitive acquisition program (CAP) for outpatient drugs and biologics under Part B, published in the *Federal Register* on March 4, 2005. Genzyme is a member of the Pharmaceutical Research and Manufacturers of America ("PhRMA") and the Biotechnology Industry Organization ("BIO") and fully supports the comments submitted by both associations. As a supplement to these comment letters, we write separately to address concerns related to our Part B products.

Genzyme is a global leader among biotechnology companies and is headquartered in Cambridge, Massachusetts. Genzyme specializes in the research and development of new treatments for rare and debilitating genetic diseases, as well as renal disease, orthopedic injuries and cancer.

Genzyme believes that the CAP program provides physicians who administer Part B drugs to Medicare beneficiaries an important option for acquiring those drugs. For physicians that are burdened with the administrative complexities and risk involved in purchasing, billing and collecting coinsurance, the CAP program offers an opportunity to eliminate these financial issues while protecting patient access to critical drugs and biologics.

Genzyme recommends that CMS fully phase-in the program by allowing all physicians to choose to participate in the CAP and to choose the categories of drugs and biologics they want to receive through a vendor, regardless of the drug category or geographic area. In accordance with the statute, CMS should clarify Congressional intent that vendors do not have

the authority to create formularies by offering only certain Healthcare Common Procedural Coding System (HCPCS) codes within a category. Instead, vendors should be clearly required to give participating physicians a broad choice of therapies, including at least one drug per HCPCS code within each drug or biologic category.

In addition to offering all physicians broad access to appropriate drugs and biologics, the CAP program must not impose excessive burdens on participating physicians. Genzyme recommends that physicians have wide latitude to use the resupply option to ensure timely access to drugs and biologics and to request an advance supply of certain therapies to treat patients whose needs cannot be predicted. Physicians must also be given the flexibility of choosing the drug categories he/she wishes to obtain from a vendor and to use different vendors for different drug and biologic categories. Lastly, CMS should recognize that the specified ceiling of 106% of the weighted ASP for composite bids is not required or authorized in the Medicare Prescription Drug, Improvement and Modernization Act (MMA) of 2003 and that it conflicts with the underlying market-based philosophy of the program.

1. All Physicians Should Have the CAP Option

The proposed rule describes several options for limiting CAP's scope during the initial phase-in period, both by drug category and geographic area. Genzyme recommends that CMS provide all specialties the choice to use the CAP program as a means of protecting patient access to Part B therapies. Many physician specialists, including the endocrinologists, orthopedists, geneticists and hematologist-oncologists that administer Genzyme products, have voiced their challenges with the current Part B system of acquiring drugs. They are currently required to navigate through the lengthy and difficult to manage process of purchasing products from wholesalers, specialty distributors or directly from manufacturers and billing the Medicare program. They are required to engage in the collection of coinsurance on drugs that can be significant for a beneficiary and a physician, while employing the physician's own working capital and bearing financial risk for non-payment for drugs. The CAP program can reduce this financial risk for all physician specialists and all should be given the opportunity to participate in the initial rollout of the program. As long as CMS can ensure that vendors will be able to provide timely access to high quality, properly stored drugs and biologics, the initial implementation of the CAP should include a broad range of drug categories to allow all specialties to participate.

2. Patients Should Have Access to Appropriate Therapies

Physicians who choose to participate in the CAP program must be given the ability to provide appropriate therapies by having a broad range of drugs and biologics to choose from to meet their patients' needs. The biotech industry understands that vendors have been urging CMS to grant them authority to construct formularies under the CAP. The authority to construct a

formulary by offering only certain HCPCS codes within a category directly conflicts with the statute and well as Congressinal intent in enacting the CAP. It also is not in the best interest of patients and providers who need access to a broad spectrum of therapies.

Specifically, the MMA statute requires vendors to supply "at least one competitively biddable drug and biological within each billing and payment code within each category for each competitive acquisition area." This provision makes clear that when a CAP category includes HCPCS codes that contain only one drug or biological, the CAP vendor must provide such product and does not have the authority to impose a formulary under which this therapy would not be included in its offer. Accordingly, Genzyme requests that CMS state affirmatively in the final rule that CAP vendors do not have the authority to construct formularies and that they must supply at least one drug or biologic within every HCPCS code that falls under a category chosen by CMS for the CAP. Genzyme believes that Congressional intent must be made clearer in the final rule.

3. Physicians Should be Allowed to Use the Resupply Option to Ensure Timely Administration of Therapies

The MMA requires CMS to establish rules that allow physicians to resupply their inventories with drugs supplied by CAP vendors when 1) the drugs are required immediately; 2) the physicians could not have "reasonably anticipated" the immediate need for drugs; 3) the CAP vendor could not deliver the drugs in a timely manner' and 4) the drugs were administered in an "emergency situation."

Although many drug and biologic regimens, such as enzyme replacement therapy or cancer treatments, must be administered on precise schedules, there are also many cases where the need for immediate administration of a drug only becomes apparent when the physician examines the patient. For instance, an orthopedist may determine upon examination that a patient's knee osteoarthritis had progressed to the point of needing a series of viscosupplementation injections. Viscosupplements tend to require three to five weekly injections depending on the selection of the therapy. Requiring a patient to return to the physician's office for the first administration, rather than offering it immediately under the resupply option, would cost both the Medicare program and the beneficiary more in addition to inconveniencing the patient.

CMS does not propose a definition of an "emergency situation," but rather asks for comment on how it should be defined. Genzyme believes that CMS should adopt a flexible definition of "emergency situation" that is broad enough to encompass the array of circumstances where an immediate, unanticipated need for a particular drug may arise. Without a process to accommodate these kinds of situations and provide patients with prompt access to needed drug therapies, physicians may decline to participate in CAP or patient care may be compromised. For

the CAP to effectively protect patient access to drugs and biologics, CMS must allow physicians the flexibility to meet their patients' needs and prevent dangerous interruptions in care.

CMS should also allow physicians to request that a CAP vendor provide an advance supply of certain drugs and biologics that physicians would only use in response to immediate patient needs. Rather than requiring the physician to purchase these drugs and biologics, the physician should be allowed to request them from the CAP vendor at the vendor's expense and submit claims as they are used.

4. Physicians Should be Allowed to Choose Which Categories of Drugs They Will Obtain Through CAP

CMS requests comment on "whether physicians must obtain all categories of drugs that a particular CAP vendor provides from the vendor, or whether the physician should be able to choose the categories he wishes to obtain from the vendor." The MMA is clear that a physician is allowed to choose the "contractor through which drugs and biologics within a category of drugs and biologics will be acquired and delivered to the physician." Congress mandated that each physician be allowed to select a different vendor for each category, rather than be limited to one CAP vendor. CMS should clarify that a participating physician will not be required to obtain all drugs and biologics from a single vendor. This clarification would affirm the intent of the MMA and ensure that physicians have flexibility in providing therapies to their patients.

5. Imposing a Composite Bid Ceiling May Discourage Vendors From Participating in the CAP Program

The requirement in the proposed rule that CAP vendors may not exceed a composite bid ceiling of 106% of the weighted ASP in a particular category seems inconsistent with the market oriented delivery system envisioned in the MMA. The MMA does not authorize such a cap, instead relying on market forces to create competition and contain costs. Genzyme is concerned that the bid ceiling may not be adequate to ensure that high quality vendors participate in the program given the important services that specialty distributors provide in the distribution of drugs and biologics. Eliminating the composite ceiling would allow the broad participation of vendors and ensure access to quality service.

G. Conclusion

Genzyme appreciates the opportunity to comment on the important issues raised in the proposed rule. We respectfully request that CMS give serious consideration to the issues raised and we look forward to working with CMS to protect Medicare beneficiaries' access to critical

drug therapies. To ensure this goal, we ask CMS to make the following improvements in the final CAP regulations:

- Provide all physician specialties the option of participating in the CAP;
- Clarify that vendors do not have the authority to construct formularies for single source therapies;
- Clarify that every CAP vendor must offer at least one drug or biologic within every HCPCS code for each category;
- Allow physicians flexibility to use the resupply option to ensure timely access to drugs and biologics to treat patients whose needs cannot be predicted;
- Clarify that participating physicians will not be required to obtain all categories of drugs and biologics from a single vendor;
- Eliminate the 106% ceiling of ASP for composite bids from vendors.

If you have any questions concerning this matter, please contact Sara Froelich or Mary McGrane at 202-296-3280.

Respectfully submitted,

Sara L Froelich

Sara L. Froelich
Vice President, Government Relations

ONCOLOGY NURSING SOCIETY

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APR 26 2005

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April 26, 2005

The Honorable Mark McClellan, MD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
445-G Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Attention: CMS-1325-P
Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B

Dear Dr. McClellan:

On behalf of the Oncology Nursing Society (ONS) – the largest professional oncology group in the United States, composed of more than 31,000 nurses and other health professionals dedicated to ensuring and advancing access to quality care for all individuals affected by cancer – we appreciate this opportunity to submit formal comments to the Centers for Medicare and Medicaid Services (CMS) related to competitive acquisition for Medicare Part B drugs and biologicals. As part of its mission, the Society stands ready to work with policymakers at the local, state, and federal levels to advance policies and programs that will reduce and prevent suffering from cancer, particularly among the Medicare population which is disproportionately affected by cancer.

We appreciate and share CMS's and Congress' concern regarding the flaws in the pre-"Medicare Prescription Drug, Improvement, and Modernization Act of 2003" (MMA) payment system for outpatient chemotherapy and agree that it needed to be reformed to ensure that the federal government and Medicare beneficiaries do not overpay for benefits or services. To that end, ONS generally supports the approach taken by the MMA to move Medicare reimbursement rates closer to the actual costs of drugs, drug administration, and related services. However, ONS has serious concerns about the implementation and effects of some of the provisions in the MMA, including the provisions related to the competitive acquisition program (CAP) – or outsourcing of chemotherapy acquisition and preparation. As requested in the Federal Register Notice, our comments are organized by the subjects/headers specified in the notice.

Issue Identifier: General Overview of CAP

The provision of quality, comprehensive cancer care requires a multidisciplinary team of professionals, including physicians, nurses, social workers, pharmacists, nutrition counselors, and laboratory technicians. Oncology nurses are on the front lines of the provision of quality cancer care, and each day they utilize highly specialized skills to prepare, administer, and monitor the effects of the highly toxic, technical, and critical chemotherapy provided to people with cancer. ONS is disappointed that in the March 4, 2005 Federal Register notice that nurses are not named among those groups with whom Research Triangle International (RTI) consulted "to obtain input on the implementation of this MMA provision." ONS commends RTI for consulting with "groups representing beneficiaries, physicians and suppliers, drug suppliers, and drug manufacturers," however, the notable absence of nursing in this list is a significant oversight, as a majority of the actual chemotherapy procurement, storage/inventory management, preparation, and administration is conducted by oncology nurses – not physicians. ONS welcomes the opportunity to work and meet with both CMS and RTI and urges both entities to reach out to our organization and oncology nurses across the country to ensure that the nursing perspective, expertise, and recommendations are incorporated into the design and implementation of the CAP.

Based on the organization's policies and principles, ONS generally opposes mandatory vendor imposition (MVI), "brown-bagging," or other "outsourcing" arrangements – such as competitive bidding – for the acquisition of prescription drugs related to chemotherapy and supportive care. Cancer care is most effective when oncologists, nurses, and patients work together to evaluate and address a patient's ever-changing health, well-being, and responsiveness to therapy, including supportive care drugs such as anti-emetics and pain medication. As blood counts, tumor size, symptoms, pain, vital signs, and other side-effects change over the course of treatment and from visit-to-visit, it is essential that cancer care providers be able to modify treatment rapidly to ensure its greatest efficacy. This requires an ability to have ready access to a wide-range of chemotherapeutic agents and supportive care drugs.

While participation in the "competitive bidding" program technically is voluntary, ONS maintains that reimbursement rates and other policy changes in the MMA may create a scenario in which – in reality – maintaining an in-office "pharmacy" is economically infeasible, and that the choice to obtain drugs from a CAP vendor for physicians will not really be "voluntary." This "forced choice" could have serious adverse effects on Medicare beneficiaries with cancer. Moreover, while ONS appreciates that the competitive bidding provision contained in the MMA seeks to save the Medicare program money, we have reservations about the true effectiveness and efficiency of such a system for chemotherapy drugs.

To that end, ONS has concerns that a competitive bidding – or outsourced – system as envisioned in the MMA and described in the proposed rule, in essence, could preclude many physicians in the outpatient office setting from being able to maintain – and have ready access to – the stock of drugs necessary to be responsive to – and able to meet – patients' changing needs. If patients' chemotherapy sessions must be rescheduled due to the unavailability of drugs, patients will face additional costs associated with another "repeat" physician office visit

on another day (which requires a separate coinsurance payment), as well as other related burdens, such as, but not limited to, additional transportation costs and inconvenience to themselves or their caregivers.

In addition, ONS members have voiced serious concerns about the human and economic resources that implementing and participating in the CAP will require. A significant amount of work will be required in the actual ordering of – and maintaining a system for – patient specific drugs. Moreover, ONS continues to have concerns that current Medicare reimbursement rates and policies do not adequately cover or include the full range of services provided by oncology nurses (e.g. staff time and supplies to reconstitute drugs, time in evaluating the patient, starting the IV, etc.). These insufficient payments – coupled with losses that could occur due to excess waste and other challenges posed by the CAP – could leave many physician office practices without adequate resources.

Of further concern is that total reimbursement for cancer care services will drop precipitously on January 1, 2006 with the phase-out of the drug administration transitional factor and the end of the quality cancer care demonstration project. ONS believes that Medicare payment fails to adequately reimburse for a number of critical services that oncology nurses provide incident to a physician's service. Moreover, ONS continues to be concerned that Medicare does not provide specific and sufficient payment for myriad other services provided by oncology nurses and social workers to people with cancer – leading to insufficient resources to support the sustained provision of comprehensive, quality community-based cancer care. To that end, ONS continues to urge CMS to revise Medicare practice expense payments to more accurately reflect and reimburse for the full range of work conducted and services provided by oncology nurses, including supportive care.

To help sustain the provision of community-based cancer care, ONS supports the extension of the quality cancer care demonstration and the associated payments while challenges and potential problems associated with inadequate reimbursement for drug administration services are addressed. However, should the demonstration be extended, ONS urges CMS to heed our recommendations made to the agency in December 2004 on the project. In those comments, ONS urged CMS to – should the demonstration be extended into calendar year 2006 – take a number of steps to ensure the improvement of the project, and ONS maintains and urges full and fair consideration of those recommendations. (A copy of the previous comments is attached to this letter for your reference.)

While ONS recognizes that CMS is proposing not to make any additional payment to physician office practices for the administrative costs associated with participating in the CAP, ONS believes that an additional payment may be warranted, as each step in the process of ordering, procuring, storing, utilizing, and billing for drugs under the CAP requires additional administrative work above that of – and different from – the current "buy-and-bill" system. Therefore, ONS urges CMS to consider providing an initial payment to help practices support the "start-up" costs associated with CAP participation. To determine the actual additional costs – and appropriate "CAP participation supportive payment" to physician office practices – ONS urges CMS to collect data on the costs imposed on practices and, as necessary, make permanent an additional payment to physician office practices to cover those additional costs.

***Issue Identifier*: Categories of Drugs to Be Included Under the CAP**

While ONS opposes "outsourcing" arrangements – such as the CAP – for the acquisition of prescription drugs related to chemotherapy and supportive care, ONS recognizes that CMS is required by the MMA to implement a competitive bidding program. Competitive bidding clearly is more complicated for drug procurement, admixture, and administration than if physician office practices maintain their own in-office pharmacies. Therefore, as in our April 1, 2004 comments (attached for your reference) during the CMS Special Open Door Listening Session, ONS proposes that instead of widespread implementation of competitive-bidding for chemotherapy acquisition, CMS should consider a smaller pilot program to gain experience and make improvements to the various CAP components (e.g. application and vendor selection procedures, claims processing, collection of coinsurance by the vendor, quality and service requirements, etc.) and see if, indeed, the system actually will be more efficient, produce cost savings, and not result in adverse effects to patients and physician office practices.

Specifically, ONS recommends that CMS begin with a regional or national CAP "test" – or "pilot" – involving a limited set of typical, or commonly utilized drugs which are administered by a physician specialty that uses drugs less intensely than oncology. This will permit the Secretary to study the competitive bidding system with regard to savings and impact on access to a subset of drugs and biologicals. As noted by CMS in the Federal Register notice, the approach of beginning with specialties that use fewer Part-B covered drugs would "allow operational issues to be addressed more gradually … allow [the agency] to identify lessons and issues before phasing in larger drug classes."

ONS has concerns about the possibility that vendors in the CAP would create – or impose – formularies and/or would be able to change the drugs offered without notice. Also of concern is that often specialty pharmacies take it upon themselves to make drug substitutions. For example, the oncologist orders Aranesp and the pharmacy sends Procrit or the oncologist orders Neulasta and the pharmacy sends Neupogen. As these drugs are not "apples" and "apples," a change in what drug is sent changes how often the patient has to receive the medications. The outside vendor pharmacist does not have the patient in front of him/her and should not have any discretion about changing the order. ONS feels strongly that there should be assurances that the outside vendor pharmacist has to fill and deliver the oncologist's order as written. In addition, ONS urges CMS to: (1) restrict the time period during which a vendor can change the list of drugs offered/available; (2) prohibit vendors from creating or utilizing formularies; and (3) require vendors to provide adequate advance notification to physician office practices of any changes to the drugs available for acquisition. ONS maintains that physician office practices should have the greatest degree of flexibility and choice of which categories of drugs they wish to obtain from a particular CAP vendor.

As part of any initial or longitudinal implementation effort, ONS urges CMS to monitor, evaluate, and report on the patient access and quality of care effects of a CAP. Moreover, as part of the monitoring of the implementation process, CMS should collect, analyze, and report on information relating to the cost of the CAP to participants (e.g. providers and beneficiaries), the burden to participants, and any other impact – anticipated or unanticipated – that may be

observed and experienced. This "feedback loop" could serve as an early warning system for any problems or potential challenges and allow for CMS to address and rectify them and/or institute any appropriate modifications or interventions, as necessary. ONS notes, however, that even if the non-oncology pilot proves successful, full implementation/application of the CAP to oncology could pose more challenging and problems could occur. To that end, ONS maintains that monitoring, measuring, and reporting of the effects of the CAP should be long-term and the information should be used to make necessary modifications and improvements to the program overtime.

***Issue Identifier*: Competitive Acquisition Areas**

Treatment plans often (some estimates suggest a third of the time) must be modified on the day of treatment due to changes in the patient's health status. As such, ONS has concerns that timely and convenient administration of treatment to Medicare beneficiaries under the CAP would be virtually impossible, as many patients likely will not be able to receive treatment the day it is prescribed – resulting in delay of treatment and patients having to travel multiple times to receive care. ONS members who have experienced other similar "outsourcing" arrangements have expressed serious doubt that the drugs would be delivered the same day the order is submitted and have indicated that it most likely would take two to three days, especially if the patient is seen very late in the day.

Delays in getting patients treated on time in the infusion rooms/centers lead to overtime hours for nurses, resulting in increased costs for the providers and Medicare, and – most importantly, greater inconvenience to patients and their family members. Many patients – particularly the elderly, those living in rural communities, and those without family in the area – cannot return another day for treatment, as they already have upended their schedules, taken off from work, rescheduled travel or other obligations, or arranged with family members or a friend for a ride to come for treatment on a particular day.

> For example, if an elderly patient developed an "infection/fever" and reported "feeling poorly" or severe flu between the time of seeing the oncologist and coming back a few days later for her chemotherapy, that could cause a delay in her treatment – especially depending on the "condition/stability" of that patient to begin with. The "sicker" she is, the more difficult it is to be very aggressive with chemotherapy. That patient has to be "worked in" to see the oncologist for another evaluation for a decision as to whether the planned chemotherapy treatment could be administered as planned for that day. If the physician determines that the patient cannot receive the planned chemotherapy and the necessary (revised) therapy is not available in the office or through the vendor via "emergency" delivery, the patient will have to return another day for care.

In addition, ONS has concerns about the insufficient requirement that CAP vendors have arrangements in place sufficient to permit shipment "at least 5 days each week for competitive biddable drugs and biologicals .... and for the timely delivery (including for emergency situations) of such drugs and biologicals in the area under the contract." As stated above, the unavailability of drugs imposes financial and other burdens – not only on the physician office

practice – but on the patient and any family members who would have to return another day for treatment.

Also, as mentioned above, ONS has concerns that many physician offices will not maintain an adequate inventory of "on-hand" drugs and biologicals to treat Medicare beneficiaries in an "emergency" situation because of the expense and burden of maintaining an on-site inventory. Our members have expressed concern that many physician office practices will be unable to obtain some drugs at a reasonable rate, because the volume of drug being ordered is minimal (leaving the purchasing practice with no bargaining power). Moreover, ONS maintains that vendors must be able to deliver drugs in a timely and appropriate fashion relative to their nature (e.g. stability); duration of the delivery time must not exceed the particular drug's stability in its appropriate shipping container and associated packaging. As such, ONS recommends that vendors be required to make routine deliveries anywhere in their service area within 24-hours of a practice's submission of a new prescription, and such 24-hour service should be available seven days a week as many physician office practices are open six to seven days a week to meet their patients' needs. Vendors should have the capacity to make same-day "emergency" deliveries to help preclude the need for patients to return another day for care.

***Issue Identifier*: Claims Processing Overview**

Experience with MVI and other outsourced preparation and delivery of chemotherapy has provided ONS members with first-hand knowledge and understanding of the challenges associated with "off-site" chemotherapy preparation and delivery, particularly when drugs are delivered to patients at their homes or work sites. As such, ONS supports the CMS proposal that "CAP vendors would deliver drugs directly to physicians in their offices." ONS also further notes that in the event that the participating practice is multi-site, that CMS should require the vendors to deliver each order to the office specified by the practice and not permit vendors to require that physician office practices designate a single address for shipments. For multi-site practices that have rural locations, this is particularly important, as many drugs and biologicals need to be maintained at particular temperatures and transporting them between practice locations would be inconvenient and inefficient, potentially exposing the drug to dangerous temperature and handling changes and therefore posing a risk to the patient.

Individual patient inventories involve a significant amount of work and many physician office practices do not have appropriate space for that type of procurement and storage system. The CAP requirements in-essence lead to the need to maintain a "per-patient inventory" which has the potential to cause excess waste – especially for multi-dose vials (e.g. Herceptin).

For example, if a practice places and order for one 440 mg vial of Herceptin (that is good for only 28 days once it is reconstituted) and the patient receives 100 mg weekly, it is unclear what the practice should – and can – do with the 40 mg that is left over. Is someone billed for the waste? If the 40 mg cannot be billed, who takes that loss? Does the patient have to be billed for the amount because the system does not allow for appropriate share of multi-dose vials? 40 mg of Herceptin can be considered more than $200 of waste. It is not clear under the CAP how to return drugs that are not used and who is responsible for the cost of

the shipping. Also, there are serious concerns about the integrity of drugs if they are being shipped back-and-forth between vendors and physician office practices and possibly back again.

In addition, our members feel that the resupply standard proposed by the agency proves too onerous and does not reflect the many common reasons why a CAP acquired drug may not have been utilized for the intended patient. As such, ONS recommends that CMS modify the standard for resupply and allow physician office practices to meet the requirement for resupply if any of the four conditions is applicable to the particular circumstance. Moreover, ONS urges CMS to provide a broad definition of an "emergency" circumstance – for example, meaning any situation deemed by the physician as requiring immediate acquisition/delivery of a particular therapy for a patient on that particular day.

In addition, we are worried about the impact that this new beneficiary co-insurance/co-payment system would have on the beneficiaries. The system by which Medicare beneficiaries pay for and receive cancer treatment would be changed significantly. If beneficiaries are unable to make their co-insurance/co-payments or are delayed in making the payments, we are concerned that vendors might not release therapies ordered for them or bring collection agency action against them, frightening them and leading them to believe they cannot continue to receive or seek care. People with cancer face numerous challenges and stresses – emotional, physical, and financial – throughout their course of treatment, and we are concerned that unless this system includes safeguards for beneficiaries related to the provision of treatment, as well as the associated payment system, their ability to receive timely, regular treatment will be threatened. As such, ONS recommends that vendors be required to fill and deliver properly ***all*** completed orders and that this requirement be made explicit. ONS supports the "furnish as written" order procedure proposed by CMS and urges that it be as administratively unburdensome as possible.

ONS feels strongly that beneficiaries need to be educated and informed about the changes in billing, billing disputes, and other related administrative processes in advance of the implementation of the change – as well as throughout the implementation phase. CMS should develop standard, easy-to-understand language that vendors be required to utilize in every bill and related written communication with beneficiaries explaining the grievance process and the method for appealing any issues they may have. This information should make clear that if the beneficiary cannot afford the coinsurance payment that alternate payment options are available from the vendor; details for how a beneficiary might receive advanced credit, reduced/negotiated co-payment rates, or assistance from outside entities for coinsurance support must be included. Vendor information also should state clearly that the beneficiaries' health care providers are not involved in the billing and do not have authority to resolve any disputes. In addition, ONS urges that the regulations should explicitly prohibit the vendor from requiring that a patient sign an Advance Beneficiary Notice in which the patient agrees to pay for the drug in the event of a coverage denial.

Moreover, as stated earlier – the insufficient payment for oncology nursing practice expenses coupled with the new administrative, clerical, pharmacy, and inventory management burdens that the CAP may impose on physician office practices – causes ONS serious concern about the

ability of physician office practices to continue to provide the full range of services and care to all patients in need. As such, ONS urges CMS to boost reimbursement for practices expenses as well as consider the provision of at least an initial additional "start-up" payment to physician office practices which participate in the CAP for at least one year to help support the implementation of the new program.

Issue Identifier: **Contracting Process – Quality and Produce Integrity Aspects**

ONS has serious concerns that patient health and safety could be compromised by the imposition of a third party with regard to drug acquisition, preparation, and delivery. By removing the principal cancer care providers from this facet of patient care, the chain of custody is broken, and oncologists and oncology nurses have no sense of security or first-hand knowledge regarding how the drugs have been prepared, handled, stored, diluted, or otherwise managed. To help ensure patient safety and well-being, we urge CMS to develop – and make available for public comment – the specific oversight structure and system of vendor accountability it intends to implement to ensure that drugs are not counterfeit or adulterated and that the drugs are prepared, shipped, and maintained in a safe and appropriate manner.

ONS members have expressed specific concern about drugs being delivered to physician office practices already reconstituted in their vials. It is difficult to envision an outside pharmacy providing drugs to practices already "admixed" and in an IV bag unless they were "next door" to the office. However, while this practice/drug preparation scenario may not be part of the planned CAP, ONS feels strongly about going on record in opposition to any CAP that would permit the preparation and delivery of drugs already reconstituted in their vials. For any drug that comes in powder form, once reconstituted, it only has a certain amount of time it is stable and – in most cases – such drugs would need refrigeration as a result. Some drugs already come in liquid form and may or may not need refrigeration to store them in their "packaged" state; if these drugs are provided through the CAP, the patient's caregiver may not be able to confirm that the drug has been prepared and stored according to instructions and safely. Anytime a drug is added to an IV bag for administration, it has a maximum of 24 hours that it will be stable in that IV bag (even less time for some drugs). For example, this could lead to therapies being thrown away if physicians or nurses cannot be assured that the drugs have been stored at the proper temperature, mixed with the proper solution, or otherwise handled appropriately – leading to terrible waste and economic inefficiencies. Some drugs simply cannot be prepared in advance because they are not stable long enough once prepared.

> For example: Avastin must be used within eight hours; Nitrogen Mustard must be used within approximately 30 minutes; and Etoposide only is stable for so many hours once placed in an IV bag unless it is made at a large dilution – this could mean having to put it in a one liter IV bag which would increase the amount of administration time (because elderly patients cannot always tolerate a lot of IV fluid in a short period of time).

Also, there are times when it is necessary to deviate from the recommended fluid volumes for a particular patient. A lung cancer patient with a compromised respiratory status could be unable to handle a large volume of fluid such as with Cisplatin or VP-16, so the decision is

made to give the chemotherapy in less fluid; if the chemotherapy already is prepared and added to IV fluids, there is no way to make the necessary adjustment, and the drug would go to waste.

> For example, a patient presents with a borderline absolute neutrophil count (ANC), the physician may choose to continue with treatment, but at a reduced dose. However, the drug delivered in the IV bag is of the higher dose. The decision must be made to (a) give the increased dose and begin supportive medications to boost the immune system, (b) give the lesser dose which will require removing a certain number of ml's from the IV bag and facing another issue of disposing of the unused portion, or (c) postpone the treatment altogether, return the IV bag/medication, and cause a loss of the patient's – and possibly caregiver's – time, as well as the loss/waste of the drug and other associated costs for the physician office practice and the health care system overall.

ONS feels strongly that there need to be reasonable and economically efficient mechanisms for delivering treatment based on the patient's well-being and specific situation. The CAP takes this important chemotherapy preparation, treatment flexibility, and quality control/assurance out of the hands of the nurses, pharmacists, and physicians within the practice and relegates it to outsiders.

All vendors must meet standard requirements for timely and appropriate delivery of drugs and should be held accountable for compliance with necessary drug delivery requirements (e.g. temperature, time/duration of stability, necessary packaging, etc.). If a vendor does not meet requirements for safe and timely drug preparation and delivery, physician office practices should have the capacity to cease use of the vendor and/or disenroll from the CAP.

This system also poses serious questions about the liability of administering therapies that were not prepared by the practice and under the practice's supervision. ONS joins with others in the cancer community calling for the requirement that vendors indemnify physicians/practices for all costs associated with any losses they cause.

Summary

ONS thanks CMS for this opportunity to provide comments on the competitive bidding of chemotherapy under Medicare Part B. ONS has serious concerns that taken together – Medicare payment policies, the current and expected nursing shortage, and the projected increase in the overall number of cancer cases over the next twenty years – pose a significant threat to the ability of our nation to provide quality cancer care to all who may be in need. The Society maintains that people with cancer should be assured access to comprehensive quality care that proves the most effective and appropriate for them.

Please know that we stand ready to work with you, Congress, and other cancer community stakeholders to craft and implement Medicare payment policy changes that provide adequate and appropriate payment for both chemotherapy and oncology nursing practice expenses,

ensure access to quality cancer care for seniors with cancer, and prove fiscally responsible for the nation.

As always, if we can be of any assistance to you, or if you have any questions, please feel free to contact us or our Washington, DC Health Policy Associate, Ilisa Halpern (202/230-5145, ihalpern@gcd.com).

Respectfully submitted,

Karen J. Stanley

Karen Stanley, RN, MSN, AOCN®, FAAN
President

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December 28, 2004

The Honorable Mark McClellan, M.D., Ph.D.
Office of the Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20001

Re: CMS-1429-FC

Dear Dr. McClellan:

On behalf of the Oncology Nursing Society (ONS) - the largest professional oncology group in the United States composed of more than 30,000 nurses and other health professionals who are dedicated to ensuring and advancing access to quality care for all individuals affected by cancer - we appreciate this opportunity to submit comments to the Centers for Medicare and Medicaid Services (CMS) on the "Demonstration of Improved Quality of Care for Cancer Patients Undergoing Chemotherapy." As part of its mission, the Society stands ready to work with policymakers at the local, state, and federal levels to advance policies that will reduce and prevent suffering from cancer, including initiatives that seek to ensure adequate reimbursement for cancer-related care paid for by the Medicare program and other public and private payors.

We applaud CMS for launching a one-year demonstration project to "assess and provide new support for the quality of care for patients undergoing chemotherapy." The quality-of-care and quality-of-life for people with cancer has been a long-standing ONS concern and this demonstration project for calendar year 2005 takes important steps forward in helping to ensure that patient outcomes are maximized. ONS has long maintained that the management of pain and other symptoms is essential to ensuring that patients not only survive a cancer diagnosis, but have the highest quality-of-life possible during and following their cancer treatment.

The three principal areas that the demonstration will address – controlling pain, minimizing nausea and vomiting, and reducing fatigue – are three patient outcomes in which oncology nurses make a tangible difference. The provision of quality cancer care requires a multidisciplinary team of professionals, including physicians, nurses, social

workers, pharmacists, nutrition counselors, and laboratory technicians. Oncology nurses are on the front-lines of the provision of quality cancer care and each day they utilize very specialized skills to coordinate and administer the comprehensive, high quality cancer treatment and supportive care Medicare beneficiaries need and deserve. Specifically, oncology nurses play an essential role in administering chemotherapy, managing patient therapies and side-effects, stabilizing patients during an emergency, documenting important information in patient charts, working with Medicare and other payors to ensure that patients receive the appropriate treatment, providing counseling to patients and family members, triaging patient questions and problems during the day, as well as during non-business hours, in addition to many other daily acts on behalf of people with cancer. As such, oncology nurses will be on the front-lines of managing, preventing and treating the three symptoms under study in the demonstration project.

We commend CMS for ensuring that non-physician practitioners – such as oncology nurses – operating within the State scope of practice laws who take care of and administer chemotherapy to oncology patients in an office-setting are eligible to participate in the demonstration project. Moreover, we appreciate that CMS has clarified that a nurse may conduct the assessment of the three patient status factors and record the results of this assessment in the context of providing an incident-to service. We have distributed information about the demonstration project to our members and have encouraged them to participate in this important endeavor.

While ONS fully supports CMS's implementation of a demonstration project aimed at improving quality-of-care for Medicare beneficiaries with cancer, we respectfully request that CMS consider the following:

- Evaluating the difference in type and level of care given to patients when they report a "little," "quite a bit," or "very much" to the assessment for any of the three symptoms being measured;
- Assessing how an individual patient's care changes (e.g. improving, decreasing) over the course of treatment and analyzing how treatment and quality-of-care compares to standards of care and treatment guidelines;
- Creating an advisory group of key stakeholders – including oncology nurses, oncologists, patients, and researchers – for the demonstration project to provide counsel to CMS on the development, implementation, and evaluation of the effort;
- Making the collected data available to stakeholders, such as ONS, so interested parties can utilize the information to maximize quality-of-care and outcomes for seniors with cancer;
- Extending the demonstration beyond calendar year 2005 so as to have access to longitudinal data;

- Adding other quality-of-life and quality-of-care measures for 2006, identified and developed through consultation with ONS and other stakeholders and public comment; and
- Waiving - or otherwise working with the Administration and Congress to eliminate or exempt the collection of - the beneficiary co-payment for participation in the study to ensure the maximum number of individuals participates in the demonstration project and that lower-income beneficiaries are not excluded from this important data collection and patient assessment effort.

Please know that we stand ready to work with you and your colleagues to craft and implement policies and programs to ensure access to quality, comprehensive cancer care for seniors with cancer. Specifically, we welcome the opportunity to collaborate with CMS staff on the implementation, evaluation, and extension/expansion of the quality-of-care demonstration project.

Should you or your staff have any questions or if we can be of any assistance to you on this or other oncology or nursing related matters, please contact us, or our ONS Health Policy Associates in Washington, DC, Ilisa Halpern (202/230-5145, ihalpern@gcd.com) or Christine Williams (202/230-5159, cwilliams@gcd.com). Thank you again for your consideration of our views.

Respectfully submitted,

Karen J. Stanley

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President

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Community Oncology Alliance

Dedicated to high quality, affordable, and accessible cancer care

APR 26 2005

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HAND-DELIVERED

April 26, 2005

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
200 Independence Avenue, SW
Washington, DC 20201

RE: CMS – 1325-P, Comments on the Notice of Proposed Rulemaking for the Competitive Acquisition of Outpatient Drugs and Biologicals under Part B

Dear Dr. McClellan:

The Community Oncology Alliance (COA) welcomes the opportunity to submit comments to the Centers for Medicare and Medicaid Services (CMS) on the proposed rules implementing provisions of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) requiring establishment of a competitive acquisition program (CAP) for certain Medicare Part B drugs.

As you are well aware, COA represents the interests of community cancer clinics, where over 80% of Americans battling cancer are treated. COA was formed specifically to support and advocate for Medicare payment reform that is balanced, appropriate, and reflective of the realities of delivering modern-day cancer care.

Previously, we provided CMS with extensive comments regarding the impact of changes in the Medicare physician fee schedule and reimbursement methodology for Part B drugs on cancer treatment. We understand that CAP was a part of the same payment reform package and that CAP was intended to help, not hurt, community cancer clinics by reducing the financial burden of drug acquisition. We also understand that CMS did not create CAP, but is mandated by the MMA to implement it.

Regrettably, we have concluded that CMS' proposed design for CAP exacerbates CAP's statutory flaws.[1] The resulting program, conceptually and operationally, can best be described as, "bad medicine and bad economics." In terms of "bad medicine," CAP:

- Gives vendors, not oncologists, control over what drugs are available, when and how they will be delivered and deprives oncologists of the flexibility to modify treatments as medically necessary.

[1] The statute prohibits a CAP vendor from delivering drugs or biologicals to a selecting physician except upon receipt of a prescription, and the vendor's payment is conditioned upon the administration of the drug. 42 U.S.C. Section 1395w-3b. As a result, electing physicians will be required to maintain paper or electronic individual inventories of drugs and biologicals. Beyond the administrative burden, individual inventories create the potential for millions of dollars of "waste" from unused and unusable medications.

- Once oncologists elect a CAP vendor, they will be locked-in to their contracts for a year, irrespective of vendors' performance.
- Gives vendors the responsibility for collecting patient co-payments and allows them to discontinue delivery of cancer drugs to oncology clinics for specific patients if co-payments are unpaid or uncollected. Putting CAP vendors between patients and their oncologists and nursing team creates unacceptable medical and legal risks to both patients and treating physicians.
- Forces patients to return for extra visits because ordering and resupply rules are too rigid. To a person fighting cancer, every second spent out of a cancer clinic living a normal, productive life is an extremely important part of the healing process.

Given Congress' timetable for CAP implementation, CMS has not had adequate time to consult with practicing community oncologists about the design of CAP. The concept outlined in the MMA may make sense in competitively bidding routine prescription drugs, but CAP simply ignores the reality of delivering complicated, chemotherapy regimens, most involving multiple, toxic drugs.

In terms of "bad economics," CAP is oblivious to the financial realities of cancer treatment in 2005. Some of the major "economic" problems are:

- Cancer care in 2005 involves increasing use of new brand drugs versus generics. There is no incentive or reason for brand manufacturers to competitively bid their drugs outside of formulary that in turn restricts access to care.
- CAP will place new administrative burdens on community cancer clinics. In addition to onerous claims process and tracking requirements, clinics will have to manage individual patient drug inventories under CAP. These new burdens are not compensated by Medicare and will increase financial pressures on CAP participating clinics.
- If community cancer clinics are unable to obtain medically necessary drugs to treat their patients or if they are unable to absorb the additional financial burden imposed by CAP, cancer patients will be sent to hospitals where treatment will be more costly.

We are extremely concerned that CMS is proposing to implement CAP first in cancer care without any cost or risk analyses. After all, we are dealing with the treatment of cancer, where life and death hangs in the balance. The current cancer care delivery system has evolved over the past 15-20 years when cancer treatment shifted from hospital-based to the outpatient, community setting. Easily accessible cancer care, combined with earlier disease diagnosis and more targeted therapy, have actually decreased the cancer mortality rate in recent years. CAP changes a time-tested, efficient delivery system with an untested concept. It is akin to allowing new cancer drugs to be introduced to clinical use without rigorous FDA clinical trials, analyses, and approval.

We are providing our comments to you in a separate document, which is attached to this letter. Section I is a summary of our major concerns. Section II includes an extensive, section-by-section analysis. Where appropriate, we have offered specific recommendations.

In closing, we urge CMS to postpone the implementation of CAP until such time as a workable framework can be developed and extensive analysis is conducted. Such actions can only be achieved if CMS takes the time to listen to community oncologists and others physicians who treat patients under Medicare Part B. As a fellow physician, you well understand our commitment to our patients to provide effective, medically necessary treatment and our concern that CAP increases burden without improving care.

Thank you again for your consideration. We welcome the opportunity to answer your questions or provide you with additional information regarding our concerns. We will make ourselves available to meet with you as soon as possible to discuss the CAP program and other critical issues facing community cancer clinics.

Sincerely,

Leonard Kalman

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CMS File No. 1325-P

Comments on the Proposed Rules Implementing the Competitive Acquisition Program (CAP) published in the Federal Register on March 5, 2005

Prepared by the Community Oncology Alliance

April 26, 2005

Part I - Introduction and Summary

On March 4, 2005, the Centers for Medicare and Medicaid Services (CMS) published a proposed rule implementing CAP for Medicare Part B drugs. The CAP program was established by the MMA and is intended to provide physicians with an alternative way of obtaining Medicare Part B drugs. Under CAP, beginning January 1, 2006, physicians who choose to participate in CAP will obtain Medicare Part B drugs from vendors who have been selected through a competitive bidding process. Under CAP, vendors, not physicians, are responsible for billing Medicare carriers and collecting beneficiary co-payments.

According to CMS, while CAP *may* provide opportunities for Federal savings to the extent that aggregate bid prices are less than 106 percent of the average sales price (ASP), an important goal of CAP is to eliminate the financial burden on physicians by providing an alternative means for physicians to obtain Part B drugs. In other words, CAP is supposed to provide an alternative for physicians who do not want to be in the business of acquiring and billing both Medicare and patients for cancer drugs.

The Community Oncology Alliance (COA), however, analyzed the proposed rule and identified a number of serious concerns regarding CMS' approach that render the program unworkable for oncologists. COA's detailed analysis and recommendations are set forth in Part II of this document. COA's major concerns are summarized as follows:

--- CMS must have CAP operational by October 1, 2005, the beginning of the annual election period. Yet, the proposed rule reflects that CMS is still very much in the information gathering stage of program development and has not yet even fully conceptualized critical operational features or implementation tasks such as developing a pricing methodology and designing and running a bidding process. The rush to meet deadline, however, seriously compromises CAP's chance for a successful launch and further, compromises the public's opportunity to comment on proposed rules as required by the Administrative Procedure Act (APA).

--- CMS' proposed claims processing system fails to relieve physicians of the cost and burden of purchasing drugs. In fact, it is more burdensome since physicians must not only file detailed claims, they also must track each drug by prescription, maintain at least a paper or electronic inventory of drugs for each patient individually, notify the vendor when a drug is not administered, provide the vendor with information to assist in the collection of deductibles and co-insurance and pursue appeals when a claim is denied – all without compensation.

---- Physicians will be locked into a contract with a CAP vendor for a year with little or no recourse if the vendor fails to perform and provide the level of service required to meet the needs of a busy oncology clinic. Oncologists rely on the timely delivery of quality drugs and biologicals to treat patients who are receiving complicated drug protocols which must be administered within a slotted timeframe to ensure efficacy of the treatment. If a vendor fails to perform, physicians must be able to immediately terminate their CAP elections with the option of either purchasing the drugs themselves or electing a new CAP vendor.

---- The proposed rule overly restricts a physician's choice of and access to medically necessary drugs. Among other issues, for multi-source drugs, the proposed rule would allow CAP vendors the option to choose which drug(s) within the class will be provided. CMS also is considering requiring physicians to obtain all categories of drugs from a particular CAP vendor (rather than allowing the physician to choose the categories of drugs he or she wishes to obtain from the vendor). Finally, the proposed rule severely limits when and under what circumstances a physician can use CAP drugs to resupply inventory and fails to provide timely access to drugs in an emergency.

---- CAP vendors, who are neither legally nor ethically responsible for the course of a patient's treatment, will be responsible for collecting Medicare copayment from secondary insurers or from patients. Should CAP vendors be unable to collect co-payments, nothing in the statute or proposed rule prohibits vendors from stopping delivery of the drugs to the community cancer clinic.

Part II - Section by Section Analysis and Recommendations

1. Overview of CAP

Implementation Tasks and Timetable

The MMA provides that CAP is to be effective on January 1, 2006. Prior to issuance of the proposed rule, CMS engaged in several activities to help the agency design and implement CAP. Specifically, CMS hired a contractor to obtain basic information, develop alternative proposals, and consult with stakeholder groups. CMS also conducted one Special Open Door Listening Session on April 1, 2004, established an electronic mailbox, and issued a Request for Information, which yielded 15 responses. Nevertheless, as noted below, the proposed rule suggests that CMS is still very much in the information gathering stage and is still deliberating various options regarding basic program operations. As a result, the proposed rule lacks specificity regarding a number of key program requirements.

Beyond the need to identify key program requirements, CMS has identified a laundry list of activities that must be completed prior to CAP's effective date, including designating or developing quality, service, and financial performance standards for vendors; creating a pricing methodology; designing and running a bidding process from solicitation through contract award; providing physicians with an opportunity to elect to participate and select a vendor; educating beneficiaries about the program; and conducting other activities specified in the statute and

described in the proposed rule. In reality, however, the CAP bidding process and the selection of vendors must be completed by fall, 2005, which is the beginning of the first annual election period.

Comment: With only eight (8) months before CAP's effective date, and less than five (5) months before the beginning of the first annual election period, COA is concerned that CMS does not have adequate time to deliberate and reach closure on key program requirements *and* complete all of the tasks necessary to initiate CAP. Furthermore, CMS' interest in broadly soliciting input on very basic issues at this stage in the CAP implementation process suggests that CMS lacks sufficient information and understanding of the drug acquisition process and its impact on community cancer care and the delivery of cancer treatment to formulate viable proposals for the CAP program.

Recommendation: While we are cognizant that Congress decreed that CAP should be effective on January 1, 2006, we strongly urge CMS to take the time it needs to fully understand how CAP can best be structured to attain Congress' objectives and benefit physicians without compromising access to drug therapies and treatment. Further, to ensure an effective launch with adequate vendor and physician participation, CMS must delay the effective date of CAP to such a time

2. Categories of Drugs to be included under the CAP

a. Categories of Drugs to be included in CAP

The MMA provides some flexibility in the development of CAP by giving the Secretary of the Department of Health and Human Services (HHS) the authority to select appropriate categories of drugs and appropriate geographic areas for the program. CMS proposes three phase-in options:

Option 1 – Under Option 1, CMS would initially implement CAP for a limited set of drugs that are typically administered by oncologists. Drugs typically administered by other specialties would be included over the next few years. CMS believes that one advantage of this approach is that it allows CMS to focus implementation efforts on one specialty with a more homogeneous set of concerns and issues. Also, by limiting the targeted drugs to those typically administered by oncologists, the physician education process would be streamlined and potentially more effective. Finally, oncologists use a high proportion of the physician-administered drugs that could be included under CAP, therefore making the program more attractive to potential vendors. A potential downside is that a focus on oncology drugs may be too narrow and would deprive other physicians of the opportunity to participate.

Option 2 – Under Option 2, CMS would choose a limited set of drugs that are typically administered by one or more physician specialties that use Part B drugs less intensively. Such an approach would allow operational issues to be addressed more gradually, but may restrict the potential benefits of the program. Further, a restricted approach may not elicit sufficient response from potential vendors.

Option 3 – Under Option 3, CAP would be implemented for all Part B drugs that are furnished incident to a physician's service regardless of specialty.

CMS states that it is not proposing any particular option at this time but is actively considering all of these options and is encouraging recommendations on other approaches for further analysis. CMS further states that it may adopt one of the options described above, or an option brought to its attention through the comment process, in the final rule. Importantly, the categories that are established for physicians to select will be the same categories that would be open for bids of potential vendors. Thus, for example, if a category embracing all drugs typically administered by oncologists is established, vendors would bid on all HCPCS codes contained in the category and a physician who elects to participate in CAP would be electing to acquire that category from the vendor.

Comment: CMS' approach violates the Administrative Procedures Act (APA) requiring that agencies must publish a notice of proposed rulemaking in the Federal Register that provides interested persons with an opportunity to participate in the rule making through submission of written comments. 5 U.S.C. § 553. It is well established that a notice of proposed rulemaking must provide sufficient factual detail and rationale for the rule to permit interested parties to comment meaningfully.[2] Here, CMS has made no specific proposal regarding the phase-in of CAP. Instead, CMS has offered three options and is seeking additional ideas from interested entities. While CMS' interest in soliciting new ideas is appreciated, contrary to CMS' own statement, it cannot adopt a proposal without giving the public the opportunity to comment on it.

Recommendation: Once CMS has decided what "phase-in" approach it will take, a second notice must be published in the Federal Register to allow for public comment before the proposal can be adopted as a final rule.

b. Allowing Vendors to Limit Availability of Drugs within Categories (i.e., formularies)

While vendors will be required to bid on all HCPCS codes within a category, (e.g. drugs used by oncologists), CMS is proposing that vendors not be required to provide every National Drug Code associated with a HCPCS code.[3] In effect, this gives a vendor permission to establish a formulary by choosing which drugs it will make available through CAP.

Comment: Cancer treatment is complex and poses many risks to patients. Although oncology drugs may be in the same class and category, they are not fungible. Active ingredients, for example, may be similar, but inactive ingredients may act quite differently when combined with other drugs in a complex, multi-treatment regimen. Certain drugs may be less effective or more costly to administer (e.g., the drug takes extra time to reconstitute, or fails to mix properly — leaving particulate matter and needed treatment, at the bottom of the bag instead of in the patient). Furthermore, different drugs within the same class or category can have different FDA

[2] Florida Power & Light Company v. U.S., 846 F.2d 765, 269 U.S. App. D.C. 377 (CADC 1988), cert denied 109 S.Ct 1952, 490 U.S. 1045, 104 L. Ed. 2d 422.

[3] Although this proposal is discussed in the preamble to the proposed rule, it is not included in the actual text of the proposed rule.

approvals and different indications for use. A prime example is Procrit and Aranesp. For certain types of treatments, some may consider these drugs to be interchangeable; however, the drugs are different because each drug has a different indication for use. Similarly, interferon drugs, while in the same category, also have different indications and FDA approvals.

When a health insurer or prescription drug plan limits access to drugs through a formulary, certain safeguards generally are required to ensure that patients are assured access to medically necessary drugs and that formularies are not overly restrictive or driven solely by pricing. For example, under Medicare Part D, formularies must be developed by Pharmacy and Therapeutics (P&T) committees. Formularies must also be non-discriminatory and must provide for exceptions and appeals. Finally, prescription drug plan sponsors are prohibited from making certain formulary changes and if formulary changes are made, plans must provide notice or a one-time supply to assist the beneficiary through transitions.

Unlike Medicare Part D, however, CMS has not proposed any minimum standards or safeguards to govern which drugs must be covered by CAP vendors within a designated category of drugs. If vendors are allowed to restrict access or are allowed to change the drugs offered without notice to the participating physicians, physicians are unlikely to elect to participate in CAP. For those that do elect to participate, if formularies become too limited, they will be forced to resort to "dispense as written" specificity for drugs and work outside of CAP through the ASP program, incurring cost and additional effort on all sides. (See additional comments below regarding CAP Operations.) Finally, we note that while CMS states in the preamble to the proposed rule that, upon request, vendors will be required to provide potential physician participants with specific information about the NDCs within each HCPCS code that it provides and that this information must also be disclosed to CMS as part of the bidding application, the proposed rule contains no such provisions.

Recommendation: The final rule must make clear that formularies are not permitted. Further, the final rule should provide that during the annual election period and upon request thereafter, a CAP vendor must fully disclose each drug that the vendor will make available pursuant to its CAP contract. In addition, vendors must be prohibited from making any changes in the list of drugs available through CAP within 90 days of the annual election period or, after the expiration of 90 days following the election period, without 90 days advance written notice to all participating physicians. Finally, physicians should have the right to opt out of CAP should a vendor fail to make proper disclosures or fail to make drugs available that the physician determines are medically necessary for the treatment of his/her patients.

c. Exclusion of drugs

Section 1847B(a)(1)(D) of the Act gives the Secretary authority to exclude competitively biddable drugs and biologicals from CAP on grounds that including those drugs and biologicals would not result in significant savings or would have an adverse impact on access to those drugs and biologicals. While the preamble to the proposed rule states that CMS has made no findings regarding these two issues at this time, and the rule merely tracks the statutory language without elaboration, neither the preamble nor the rule identify how CMS intends to monitor either savings or adverse impact on access.

Comment: CAP is a new and untested acquisition program for Part B drugs — a significant percentage of which are drugs to treat cancer. Timely, clinically effective treatment is critical to cancer care and in its absence, death is likely. CMS does not know what impact CAP will have on access to oncology drugs or oncology practices. Further, CMS does not know whether CAP will actually produce cost savings.

Recommendation: Given the high stakes involved, we believe it is imperative that CMS commit to and identify a methodology for monitoring how CAP affects the impact on oncology practices, including access to treatment and whether there is any impact on cost.

3. Competitive Acquisition Areas

The law authorizes the Secretary to establish appropriate geographic regions or "competitive acquisition areas" within which to conduct CAP competitions. Competitive acquisition areas constitute the geographic boundaries within which entities will compete for contracts to provide competitively biddable drugs. The size of the geographic area will be a crucial factor in determining the number of entities that bid for and ultimately are awarded contracts.

CMS has proposed several basic options for defining the competitive acquisition area. These include: (1) establishing a national competitive acquisition area, (2) establishing regional competitive acquisition areas; and (3) establishing statewide competitive acquisition areas. According to CMS, a large, national acquisition area is attractive to vendors because it is less administratively burdensome and offers the greatest opportunity to gain market share. At the same time, however, a large acquisition area would likely discourage smaller regional drug distributors from participating in CAP, thereby reducing competition. Sub-national regions offer an opportunity to implement CAP in stages, bringing one region into the program at a time. This approach might permit CMS to work out problems in the early stages that would be important to gaining physician and vendor participation. A state approach is attractive because it uses clearly defined geopolitical borders that coincide with current vendor licensing requirements. A state-based approach could also support a geographic phase in of the program.

Comment: CMS is considering all of the above options and is also soliciting additional ideas. While all of the proposed options have merit, the biggest problem with CMS' approach is that CMS may violate the APA should it adopt a proposal that has not been published and subjected to a period of public comment.

Recommendation: Once CMS has decided how to define a "competitive acquisition area," a second notice must be published in the Federal Register before the proposal can be adopted as a final rule.

4. Statutory Requirements Concerning Claims Processing

a. Physician responsibilities and burden

Under the proposed rule, 42 C.F.R. §414.908, physicians will be given the opportunity to select an approved CAP vendor on an annual basis. Physicians must complete and sign a CAP election agreement. In addition, the physician will be required to submit a written order or prescription to the approved vendor. CMS is proposing that each drug order be accompanied by the following information:

* Date of order
* Beneficiary name
* Physician identifying information
* Drug name
* Strength
* Quantity ordered
* Doses
* Frequency/instructions
* Anticipated date of administration
* Beneficiary Medicare information/Health insurance (HIC) number
* Supplementary Insurance info
* Medicaid info
* Shipping address
* Additional patient info: date of birth, allergies, Ht/Wt/ICD-9 etc.

CAP participating physicians must also provide information to the approved vendor to facilitate collection of applicable deductibles and coinsurance, notify the vendor when a drug is not administered, agree to file a "clean" Medicare claim within 14 days of the date of drug administration that includes the name and HCPCS code of the drug administered, the prescription number for each drug administered, and the date of service, and agree to submit an appeal accompanied by all required documentation necessary to support payment if the participating CAP physician's drug administration claim is denied. Physicians will also have to maintain a separate electronic or paper inventory for each CAP drug obtained.

No provision is made to compensate the physician for any of the above activities. Yet, if a vendor is not paid on claims, the vendor may appeal to the designated carrier to counsel the responsible participating CAP physician and if the problem persists, the vendor may ask the carrier to investigate the physician's performance and recommend the suspension of the physician's CAP election agreement. While the proposed rule does provide for reconsideration and appeal of a physician's exclusion, if the carrier's decision is ultimately upheld, "CMS publishes a final reconsideration determination against the participating CAP physician in the Federal Register." Proposed 42 C.F.R. § 414.916(b).

Comment: The CAP process creates a dramatic and operationally significant change in how physicians acquire Medicare Part B drugs. When ordering from a non-CAP vendor, physicians stock a single, centralized, inventory. CAP requires each practice to order drugs and track inventory on a prescription basis for each patient, track the date of administration, bill claims within 14 calendar days of administration and share information with vendors to assist them in collecting co-payments.

For a program that was designed to get physicians out of the drug acquisition business, CAP does little to lessen the administrative burden on physicians. In fact, we believe that it increases the burden. At the same time, it strips physicians of any claim to payment. Moreover, the reward for signing on as an unpaid agent of the vendor potentially is investigation and a public pronouncement of exclusion from the program.

Recommendation: CMS must restructure CAPS' proposed claims process and tracking requirements to significantly reduce the administrative burden on physicians.

b. Written order or prescription

The statute (MMA) provides that the contractor shall not deliver drugs and biologicals to a selecting physician except upon receipt of a prescription for such drugs and biologicals, and such necessary data as may be required by the Secretary to carry out this section. The statute further provides that this section does not require a physician to submit a prescription for each individual treatment, or change a physician's flexibility in terms of writing a prescription for drugs or biologicals for a single treatment or course of treatment.

For purposes of CAP, CMS has chosen to interpret the term "prescription" to include a written "order" submitted to the vendor. CMS states its intention not to restrict a physician's flexibility when ordering drugs from a CAP vendor or to require that a physician participating in CAP would order drugs differently from a CAP vendor than he or she would a non-CAP vendor.

Comment: As proposed, a CAP "vendor" will supply pharmaceuticals to a physician's office for a particular beneficiary (patient). The "vendor" then submits a claim with a prescription number for the pharmaceutical agent to a designated carrier. That claim must be matched to a claim filed by the physician that shows the date of administration by the physician. This is not a typical supplier arrangement but rather describes the "filling" or dispensing of a "prescription" for a specific patient.

There are three problems with this approach. First, federal and state law make clear that only a licensed pharmacist may dispense a prescription. Second, requiring CAP participating physicians to maintain individual, patient-specific inventories will further increase costs substantially to physicians. Based on the fact that approximately one-third of treatment regimens are switched during the treatment cycle, there will be a significant waste problem that will increase waste disposal costs to physicians and increase drug reimbursement costs to Medicare. Third, physician billing systems are not set up to handle prescription numbers on billing claims, thus major and costly system retooling will be required.

Recommendation: It is clear that the statute (MMA) very specifically uses the word "prescription," which cannot be loosely interpreted by CMS to mean an "order."

c. Order splitting

CMS proposes allowing the physician to place an order for a beneficiary's entire course of treatment at one time but allow the vendor to split the order into appropriately spaced shipments.

According to CMS, the vendor would create a separate prescription number for each shipment and the physician would track each prescription separately and place the appropriate prescription number(s) on each drug administration claim.

Comment: It is unclear how CMS could authorize a vendor to split a shipment of pharmaceuticals needed to treat a patient without the express consent of the physician who order the drugs or under what licensing authority a vendor would be allowed to create prescription numbers. How does the vendor know how to "appropriately" space shipments? Further, allowing the vendor to split shipments creates additional administrative burden for the physician and clinical staff administering the treatment.

Recommendation: Vendors should be prohibited from splitting shipments unless approved by the physician who orders the drugs.

d. Inventory resupply

CMS has proposed that drugs acquired under the CAP may be used to resupply inventories but only if the physician can demonstrate all of the following to the Secretary: (1) the drugs are required immediately, (2) the physician could not have anticipated the need for the drugs, (3) the vendor could not have delivered the drugs in a timely manner, and (4) the drugs were administered in an emergency situation.

Comment: The standard for allowing physicians to resupply inventories with CAP drugs is too onerous and does not take into consideration certain common reasons why a CAP drug may not have been used. About one-third of the time, a scheduled treatment for an oncology patient does not happen as planned. This may be due to scheduling issues or, more commonly, the patient's needs changes and an alternative regimen is indicated. In most cases, such changes cannot be categorized as "emergencies." Yet, it is highly unreasonable and very costly to require a patient, who has already been examined and tested, to return in another day or two, in order to obtain a new mixture of drugs, rather than obtain treatment from the physician's inventory. The resupply rules will be especially difficult for rural oncology clinics where patients in debilitated health must travel long distances to obtain treatment. Delaying treatment and requiring patients to return on another day or wait long hours in order to receive new shipments of drugs acquired through the CAP vendor, is an enormous inconvenience to the patient and a cost to the practice. More importantly however, delaying treatment can adversely affect patients' health and ultimately drive up health care costs.

Recommendation: Physicians should be permitted to resupply their inventories if any one of the four conditions is applicable.

e. Unused drugs

CMS proposes that, if for some reason, the CAP-acquired drug cannot be administered to the beneficiary on the expected date of administration, the physician would notify the vendor and reach an agreement on how to handle the unused drug, consistent with state and federal law.

Comment: CMS' proposal ignores the fact that most pharmacy regulations indicate that a drug, once dispensed in a patient's name, may not be returned, reused, or reshelved. The conversion of oncology drug inventories from a single, centralized, non-patient specific inventory to a patient-specific, individualized inventory creates the potential for millions of dollars of "waste" from unused and unusable medications.

Recommendation: We understand that the requirement that a vendor only provide drugs to a participating CAP physician prohibition based upon a prescription is statutory. Nevertheless, we urge CMS to work with Congress to address impediments to a viable CAP program.

f. Uncompensated costs

One of the goals of CAP is to reduce the financial burden of drug acquisition on physician practices. However, as long as chemotherapy and other therapies to treat cancer are incident to a physician's services, physician practices will still incur costs associated with drug handling and inventory. The preamble to the proposed rules, for example, states, "the drug and prescription number would be shipped to the physician and would be maintained until the date of drug administration." However, no provision is made to compensate the physician for these costs.

Comment: At a recent MedPAC meeting, MedPAC staff identified the costs of drug handling and inventory in the hospital outpatient setting at 26% to 28% of drug costs. Oncology practices have long maintained that drug handling and inventory costs run about 12% of total drug purchase expenditures. While the CAP program does not eliminate these costs for oncology practices, physicians are not compensated for these costs under any other fee schedule.

Recommendation: CMS must recognize and compensate oncologists for the costs of drug handling and inventory.

g. Furnish as written

CMS proposes that when a CAP participating physician has determined that it is medically necessary to use another brand of product within the HCPCS or a product with an NDC that is not being furnished by the vendor, that the physician be allowed to bill for the drug under ASP. The physician would place a "furnish as written" modifier on his or her claim form and bill the Medicare carrier for the drug and the administration fee.

Comment: We support CMS proposal to permit physicians to obtain a drug under the ASP methodology in "furnish as written" cases when medical necessity requires that a specific formulation of a drug be furnished to the patient and the vendor has not been contracted to furnish a specific formulation of a drug or product defined by the product's NDC number. However, we are concerned that physicians are still subject to post payment reviews and carrier determinations that a specific NDC number was not medically necessary. This process takes the medical decision-making completely out of the physician's hands, yet it is the physician who holds the responsibility and the liability for the quality and effectiveness of drugs used for patient care, and has access to the full information.

Recommendation: CMS must make clear that "furnish as written" orders are reviewed under the same standards and process used under Medicare Part B for non-CAP drug acquisitions.

h. Physician choice of drug categories

CMS is seeking comments on whether physicians must obtain all categories of drugs that a particular CAP vendor provides from the vendor, or whether the physician should be allowed to choose the categories of drugs he wishes to obtain from the vendor.

Comment: CAP vendors may create formularies that are inconsistent with the physician's preferred medical practice, or may ignore certain variations in drug approvals or indications within categories. Oncology care is so complex that without the flexibility to deselect certain categories, quality and patient access risks increase dramatically. Furthermore, promoting choice will increase competition among vendors and should have a positive impact on quality and price.

Recommendation: COA strongly recommends that physicians be given a choice of which categories of drugs to obtain from a particular CAP vendor. There is no basis for implementing formularies.

i. Collecting beneficiary co-payments

The statute requires that the vendor bill Medicare and the beneficiary, and that the beneficiary may not be billed until after the drug has been administered to the beneficiary by the physician, who has filed a claim for the drug administration. CMS is proposing that the vendor be allowed to bill the beneficiary and/or his or her third party insurance after drug administration has been verified by matching the physician claim with the vendor claim using the prescription number, and final payment is made by the Medicare program.

Comment: Despite the impact on cash flow, community oncologists generally are reluctant to refuse to treat a patient who cannot afford to pay a co-payment. Vendors, however, are not ethically or legally responsible for the course of a patient's treatment. If a vendor is unable to collect co-payments from a patient, nothing prohibits the vendor from stopping delivery of drugs to the physician's office. Allowing vendors to stop delivering drugs to an outpatient setting is likely to endanger patients or force them into more costly in-patient settings for treatment. Further, physicians could be exposed to liability if the physician is unable to complete a course of treatment because a vendor is refusing delivery.

Recommendation: The final rule must make clear that vendors cannot refuse to deliver drugs because they are unable to collect co-payments. Alternatively, if CMS does allow vendors to stop delivering drugs, this must be made very clear to physicians during the CAP election period that the vendor may suspend treatment to any patient not paying their co-insurance. Additionally, physicians must be permitted to immediately opt out of CAP and obtain drugs through the ASP system in any single case where a vendor has decided to not ship drug(s) for a

patient not paying the Medicare co-payment or if the patient's secondary insurance carrier has denied the claims.

5. Contracting Process-Quality and Product Integrity

Vendor Quality Control

Sections 1847B(b)(2)-(3) of the MMA makes clear that vendors must meet financial and quality of care requirements aimed at assuring the stability and safety of CAP. The statute also provides that vendors have sufficient capacity to acquire and deliver drugs within a geographic area, to deliver drugs in emergency situations, and to ship drugs at least 5 days a week. The MMA also requires that the criteria for awarding vendor contracts include the vendor's ability to ensure product integrity. CMS correctly notes in the preamble that physicians would be reluctant to participate in CAP if they have little confidence that CAP vendors would be reliable and provide quality CAP products. The preamble further states that CMS seeks to "define a set of overall financial and quality standards that would ensure that reputable, and experienced vendors are chosen to participate in CAP and states we propose that CMS be allowed to suspend or terminate a vendor's contract if the vendor falls out of compliance with any of these quality requirements."

Unfortunately, the proposed rule does not identify those standards. Rather, the proposed rule states only that CMS will select approved vendors based upon certain criteria including but not limited to the "ability to ensure product integrity," "financial performance and solvency," and "record of integrity and the implementation of internal integrity measures." Proposed rule at 42 C.F.R. § 414.908(b).

On the other hand, proposed rule 42 C.F.R. §414.916(d) provides that issues regarding quality and service that relate to the vendor's performance raised by the participating CAP physician are treated through the vendors own internal grievance process. If the approved vendor does not resolve a quality issue to the participating CAP physician's satisfaction, the participating CAP physician may escalate the matter to the designated carrier. Unlike the unpaid physician who is subject to investigation and exclusion, CMS merely provides that the "designated carrier attempts to develop solutions that satisfy program requirements and the needs of both the participating CAP physician and the approved vendor." Proposed 42 C.F.R. §414.916(d).

Comment: Vendors are being paid to deliver highly volatile and, at times, toxic drugs to physicians who need them to treat critically ill patients. It is essential that vendors be held to the highest standard for quality and performance. Physicians, who will be dependent on the vendors to obtain these drugs, need to know that when complaints are raised about poor quality and performance that vendors and CMS will take them seriously. It is unrealistic to believe that physicians will participate in CAP if there is no effective process for addressing quality concerns and if they believe they have no recourse if a vendor is not performing as expected. It is unsettling and contrary to good business practice that physicians are locked into their choice of the CAP vendor(s) for a year regardless of performance and quality.

Recommendation: CMS must strengthen the rules pertaining to quality and performance standards of vendors and clarify the procedures that will be used to investigate allegations

involving the poor performance of vendors. Vendors who fail to perform should be subject to investigation and sanction, up to and including exclusion from the program.

We also recommend that CMS develop standard "hold harmless" language for the CAP election agreement that ensures that participating physicians are held harmless for the negligence and non-performance of CAP vendors.

Finally, CMS must make clear that physicians may disenroll from CAP at any time, especially in cases of quality non-performance.

6. Bidding Entity Qualifications

a. Vendor experience and capabilities

Under the proposed rule, 42 C.F.R. § 414.908(b)(1)(iv), vendors are expected to show a history of delivering Part B injectable drugs for at least 3 years.

Comment: Oncology drugs are complex medications/chemicals, with strict parameters for handling and storage. Experience with other drugs does not guarantee successful experience with oncology drugs, and the risks and liability for Medicare patients and physicians is too great to allow inexperienced vendors the responsibility of handling oncology and cancer-related supportive care drugs.

Recommendation: A CAP vendor should be required to demonstrate a history of at least 3 years of delivering each category of drugs for which they submit a bid.

b. Timeframes for routine and emergency shipment

CMS is seeking comments on how to define timely delivery for routine and emergency drug shipments. CMS is proposing that routine shipments of drugs furnished under CAP would occur within one or two business days. However, the duration of the delivery time period must not exceed the drugs stability in appropriate shipping containers and packaging. CMS also proposes that emergency drug orders be furnished on the next day for orders received by the vendor before 3 p.m. (vendor's local time). CMS is seeking comments on the feasibility of providing same-day deliveries received for emergency situations.

Comment: Same day deliveries are feasible and necessary.

Recommendations: Vendors should be required to have the capacity to make same day deliveries when drugs are needed on an emergency basis. At the time the drug is ordered, the physician should receive a commitment from the CAP vendor for a day and time of delivery, and vendors must be held accountable for compliance to that commitment.

CMS must make clear that physicians may disenroll from CAP at any time, especially in cases of delivery non-performance.

c. Conflicts of Interest

The CMS proposal sets forth a code of conduct for CAP vendors, and identifies a conflict of interest as being "where a drug vendor, its representative, or contractor provides a product or service for a Medicare provider or beneficiary and the drug vendor, representative or contractor has a relationship with another person, entity product or service that impairs or appears to impair the drug vendor's or contractor's objectivity to provide the Medicare covered product or service."

Comment: The creation of formularies for the purpose of steering market share toward one drug in a category over another in response to contracting discounts and rebates would appear to meet this definition of conflict of interest. If physicians are required to acquire drugs within categories as defined and by the CAP vendor, and the CAP vendor offers only a limited selection of the possible drugs, the CAP vendor has restricted the availability of drugs for its financial gain, and to the detriment of access to care for Medicare beneficiaries and their physicians.

Recommendation: Formularies should not be allowed.

7. CAP Bidding Process – Evaluation and Selection

a. Composite Bid Process

CMS proposes employing a composite bid process. The composite bid would be implemented in two steps. First, bidders would have to demonstrate that they meet certain quality and financial thresholds. Second, each bidder would submit its bid constructed by weighing each HCPCS bid by the HCPCS code's share of volume of drugs in a particular drug category during the prior year. The calculated composite bid would be equal to the average price per HCPCS unit for drugs in that category. CMS would then select up to five bidders, based upon price, for a drug category in each competitive acquisition area. However, CMS would not select any bid for a category that is higher than 106 percent of the weighted ASP for the drugs in that category.

Comment: As proposed, the bid process automatically eliminates drugs that are not obtainable at significant savings to the Medicare program. The result is that only the cheapest and possibly least usable versions of a drug in a category will be made available through CAP vendors.

Recommendation: CMS must revise the bid process to avoid a race to the bottom, where price considerations trump quality and efficacy concerns. Giving physicians choice and the ability to "walk with their feet" should help make vendors more sensitive and responsive to quality concerns.

b. Drug administration, waste, spillage, and spoilage

The bidding process also specifically excludes recognition of any costs related to the administration of the drug or wastage, spillage, or spoilage in submitted bids.

Comment: Wastage, spillage, and spoilage are part of the cost of treating cancer patients with drug products that are highly toxic and unstable.

Recommendation: While we recognize that the exclusion of drug administration costs, wastage, spillage, and spoilage are statutory, CMS must adjust payments to physicians for services to more accurately reflect their costs.

8. Physician Election Process

Pursuant to proposed 42 C.F.R. § 414.908, physicians will be asked to make an election and select a qualified CAP vendor on an annual basis by October 1. Once selected, the physician will only be able to go to another vendor if the approved vendor ceases to participate in CAP, or other exigent circumstances defined by the Secretary such as when the CAP physician relocates to another competitive acquisition area or leaves a group practice that is participating in CAP.

Comment: While the statute does provide for an annual election, nothing in the statute requires or supports the use of a "lock-in" period for physicians. CMS must be mindful that vendors would be inclined to charge higher rates to their captive customers if a lock-in period is required, while physicians are unlikely to sign up for the program if they cannot leave it at will. This is a new, untested program. If physicians develop serious concerns about the vendor, or the program, or unanticipated costs of supporting the program, as small businesses with a low capacity for financial risk, they need the flexibility to depart.

Recommendation: CMS must make clear that physicians may disenroll from CAP at any time.

9. Beneficiary Education

Beneficiaries are likely to be confused by the CAP program. CAP co-payment collection policies also may lead to denials and reduced access to care for some Medicare cancer patients. To educate beneficiaries, CMS is proposing to develop a beneficiary-focused fact sheet, and to update existing materials, to reflect these changes. The fact sheet would be available for physicians who elect to participate in the CAP to provide to beneficiaries at the time of service. CMS seeks comment on the administrative burden associated with this activity. CMS is not proposing any additional options for specific outreach to beneficiaries.

Comment: Patients rely on their physicians to guide them through the treatment process, and any confusion regarding billing or disruption of care will send patients immediately back to the physician office with a variety of physical, financial, medical, and psychosocial issues.

Recommendation: CMS should conduct outreach and beneficiary education to patients receiving treatment under Medicare Part B.

10. Collection of Information Requirements

CMS is estimating that physicians will need 15 minutes each to fulfill the application requirements.

Comment: At COA, we believe the decision process will actually be far more complicated and take much longer than 15 minutes. As stated elsewhere in the CMS proposed rule, practices will need to evaluate the costs of purchasing and acquiring drugs under the ASP option, and compare the costs of acquiring drugs under the CAP program, plus evaluate discrepancies between the drugs now selected for patient care and whatever specific drugs are carried under the CAP vendor formulary – and assess any relevant issues for patient care and operational burdens. The CMS proposed rule assumes that physicians must maintain a separate electronic or paper inventory for CAP drugs, but reality dictates that a physically separate inventory will also be needed, with all the attendant costs.

Recommendation: CMS should revise its estimate to reflect the additional time it will take physicians to evaluate CAP. CMS must fully analyze the application requirements and administrative costs by conducting a test with real community oncology practices and reporting back on the results.

11. Regulatory Impact Analysis

For purposes of the RFA, physicians and non-physician practitioners are considered small businesses if they generate revenues of $8.5 million or less. According to CMS, there are in excess of 20,000 physicians and other practitioners that receive Medicare payment for drugs. These physicians are concentrated in the specialties of oncology, urology, and rheumatology. Of the physicians in these specialties, approximately 40 percent are in oncology and 45 percent are in urology. CMS was unable to draw any specific conclusion regarding the impact of this proposed rule on physicians because it depends on what drugs they provide to Medicare beneficiaries, whether the drugs will be included in the CAP program, and whether the physician chooses to obtain drugs through CAP.

Comment: While we agree that certain impacts are dependent on how individual physician's react to the program, their own practices, and on information that is not yet known, we believe that overall, CAP will reduce reimbursement to oncologists, increase administrative and pharmacy costs, and ultimately affect access to treatment as more clinics are forced to close and send their patients to more costly hospital settings. Physicians who feel compelled to participate in CAP will find they will need to absorb more uncompensated costs including unreimbursed drug handling and inventory costs and the increased administrative burden of the new ordering and claims processing system. In sum, the burden to the physician and the related costs actually increase under CAP due to the need for separate inventory management and running of concurrent inventories — both for staff and facility resources.

Recommendation: CMS should do a complete impact analysis that both examines and quantifies the true cost of CAP to a community oncology practice and also quantifies the overall impact of CAP on the delivery of cancer care in this country.

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THE AMERICAN SOCIETY OF HEMATOLOGY
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APR 26 2005

April 25, 2005

Mark McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services Department of Health and Human Services
Attention: CMS-1325-P
Room 415-G, Hubert H Humphrey Building
200 Independence Ave.
Washington, DC 20201

RE: Comments on the Proposed Rule for Competitive Acquisition of Outpatient Drugs & Biologicals Under Medicare Part B

Dear Dr. McClellan:

The American Society of Hematology (ASH) appreciates the opportunity to comment on the proposed rule establishing the Competitive Acquisition Program (CAP) for drugs administered in physician offices, which was published in the *Federal Register* on March 4, 2005. ASH represents approximately 10,000 hematologists in the United States who are committed to the treatment of blood and blood-related diseases. These diseases include malignant disorders such as leukemia, lymphoma, and myeloma as well as non-malignant conditions such as anemia, thrombosis, and bleeding disorders. Drugs covered by Medicare Part B represent a substantial portion of the drugs used by our practicing members, and, therefore, the Society is very interested in the design and implementation of the CAP.

We recognize that the CAP program is entirely voluntary on the part of physicians. We also appreciate the fact that its objective is to reduce the financial exposure for physicians who face declining reimbursement due to the change in payment for drugs to 106 percent of the average sales price (ASP). However, for the CAP program to be a truly viable option and in order to preserve high quality care to Medicare beneficiaries, we urge consideration of the following recommendations.

CLAIMS PROCESSING OVERVIEW

Information To Be Submitted To The Vendor

To minimize unnecessary paperwork and to make less the administrative burden on physicians, we urge that CMS carefully review all the information

that is required to be submitted to the vendor and assure that it is necessary for claims processing and/or program integrity purposes. For example, does the vendor need information on the patient's allergies, height and weight, the ICD-9 diagnosis code, etc., to fill the prescription order?

Handling Unused Drugs

Because of changes in the patient's condition, adverse reactions or the need to revise the course of therapy, the issue of how unused drugs will be handled is a particular problem for oncology drugs. Any of these reasons could result in a decision not to administer the prescribed drug. Moreover the fact that a drug will not be provided on the anticipated date does not mean the drug will go unused. We urge CMS to work closely with ASH and other affected specialty societies over the next few months to establish policies for dealing with this issue that will be equitable and practical for both the physician and the vendor alike.

Administrative Costs

For physicians participating in the CAP program, there may be some modest reduction in the staff costs associated with billing the program for drugs. However, we absolutely disagree with the statement on page 10755 of the proposed rule that the CAP program will not create additional burdens on physicians. Actually, the opposite is true. Every practicing physician who has reviewed this proposal concludes that that the net impact will be to add significantly to the administrative costs of operating an oncology practice. The added costs flow from the need to maintain a dual ordering and inventory system, the costs incurred from the need to match the physician's and the vendor's bills, and the potentially burdensome rules dealing with the disposition of unused drugs. We suspect that these added costs and administrative headaches would cause most physicians to decide not to enroll in CAP despite the financial benefit in not having to bill for drugs.

We would urge that CMS consider establishing an administrative service fee to be paid to physicians who enroll in CAP to offset some of these added costs. A Category II HCPCS code could be established for this purpose. To keep the processing costs to a minimum, CMS could provide for the code to be billed periodically, say, monthly. We would think the costs for these payments could be absorbed by CMS from the savings associated with reduced drug expenditures flowing from the CAP.

Requirement For Vendor To Fill All Orders

It is implicit in the proposed rule that a vendor must fill all physician orders, but ASH recommends that this requirement should be explicit. Vendors may be tempted to refuse filling a particular order for various reasons, for example, the patient involved has not paid coinsurance owed to the vendor, the Medicare carrier has denied coverage of a similar previous order, the vendor thinks that the carrier might deny coverage. ASH believes the rule should state explicitly that the vendor may not refuse to fill a properly completed physician's order for any reason. Similarly, the final rule should provide that

the vendor cannot require the patient to sign an advance beneficiary notice, in which the patient agrees to pay for the drug in the event of a coverage denial.

Time for Submission of Claims

The proposed rule states that the physician would be required to submit all claims for drug administration services within fourteen days of the date of service. While ASH understands the need for prompt submission of claims because the vendor is not paid for the drug until the drug has been administered, the Society believes the proposed schedule is not feasible for many practices. ASH recommends that drug administration claims be required to be submitted within 30 days after the date of service.

CONTRACTING PROCESS – QUALITY AND PRODUCT INTEGRITY ASPECTS

Liability

We are concerned that prescribing physicians might be held liable for errors on the part of a CAP vendor due to mistakes in the drug delivered, contamination of the product, etc. These "errors" are outside of the physician's control. We think that the contractual agreement should make it clear that (1) the vendor is solely responsible for such errors, and (2) the vendor needs to maintain adequate liability insurance to indemnify a physician for any damages from suits which might result from the provision of the drug. This would, of course, not indemnify the physician where the physician or staff is the proximate cause of the mistake such as in mixing the agents.

Vendors Should Be Prohibited From Opening Containers

ASH believes the final rule should address the authority of vendors to open drug containers. ASH believes any compromise of the drug packaging integrity would be unacceptable. The final rule should clearly require vendors to ship products to physicians in containers that are unopened and otherwise in the same condition as received from the drugs' manufacturers.

CAP BIDDING PROCESS – EVALUTATION AND SELECTION

Availability Of New Drugs

We presume that at the time physicians are considering participating in the CAP, they will have a full understanding of the drugs that will be provided by the vendor in various therapeutic categories. We also assume that vendors will be prohibited from eliminating any drugs in the vendor's "formulary" during the year except perhaps where a drug has been taken off the market. We do, however, have a question about the handling of new

drugs, which were not considered by vendors in their composite bids or which were not on the market when physicians were asked to make the participation decision.

To assure that Medicare beneficiaries have access to the most current drug therapy, ASH recommends that CMS require that vendors add all new drugs to the list of drugs covered under the CAP. So as not to disadvantage the vendor, we would recommend that CMS reimburse the vendor for these drugs at a rate that fully covers their costs. Since ASP pricing may not be initially available for new drug products, CMS might want to consider basing the payment rate on the basis of actual vendor invoices.

PHYSICIAN ELECTION PROCESS

Option To Terminate Agreement

A decision to participate in the CAP program is generally irrevocable for one year with no ability to "opt out". We recognize that under the proposed rule, vendors can be terminated for cause and that some administrative processes are being established to handle disputes between a physician and a vendor. However, the CAP program is a radically different way to provide drugs to beneficiaries and is fraught with many potential problems. We think there would be greater willingness to participate in this program if physicians did not feel "locked in" to their election for a one-year program. At the same time, we appreciate the fact that vendors will need some predictability for business planning purposes. We think a reasonable balance would be to provide for the first year only that physicians be allowed to withdraw their election CAP for any reason after the first 3 months of the program. This will give vendors a chance to work through some of the inevitable start up problems inherent in any new program and for physicians to have had some meaningful experience with the vendor.

ADDITIONAL COMMENTS

In addition to the comments above, the Society feels very strongly that CMS needs to address two important issues outside the proposed rule that will be affected by the CAP: the impact of the CAP on the calculation of the Average Sales Price (ASP) and how to protect beneficiaries who cannot afford drug copayments.

Impact on Average Sales Price

If by virtue of their purchasing power, vendors are able to secure very favorable drug pricing from manufacturers, this presumably could lead to a reduction in future ASP levels. However, physicians not participating in the CAP would not have access to this pricing. Since ASP is supposed to represent the price that a drug is generally available to physicians, we would urge that CMS have manufacturers exclude sales to the vendors from the calculation of ASP.

Protection of Beneficiaries

We are very concerned that beneficiary's ability to receive services could be jeopardized in situations where the beneficiary is unable to pay the coinsurance on very costly oncology drugs. Currently, most, if not all, hematologists will continue to provide services to beneficiaries who do not have Medigap insurance who are unable to pay the 20 percent coinsurance. Coinsurance is a particular problem for cancer patients given the extremely high cost of the chemotherapy agents and the duration of the treatment. We are doubtful that all vendors will have the same sensitivity to beneficiary needs as physicians and their staff who have developed a close and personal relationship with the patient and the family. We believe that unless adequate protections are in place to protect beneficiaries, including limiting vendor collection efforts, undue pressure will be placed on beneficiaries who are unable to pay the coinsurance. In addition, some vendors may try to exert pressure on the physician to move the patient to a hospital setting and/or substitute less costly therapy. We strongly urge that CMS establish policies to guard against this practice. This should include establishing collection standards in the contractual agreement and establishing a monitoring program to detect instances of such behavior.

Thank you for the opportunity to submit these comments.

Sincerely yours,

James N George

James N. George, MD
President

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PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION

PCMA

April 26, 2005

APR 26 2005

The Honorable Mark McClellan, M.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1325-P
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: File Code CMS-1325-P

Dear Dr. McClellan:

On behalf of America's pharmacy benefit managers (PBMs), the Pharmaceutical Care Management Association (PCMA) appreciates the opportunity to submit comments on the Competitive Acquisition Program (CAP) for outpatient Part B drugs and biologics. PBMs are the leaders in providing access to specialty drugs including injectible, infused and biologic products.

Our detailed comments below focus on these general areas:

- **Incremental approach-** The CAP program represents a large scale fundamental change in the drug delivery system for Part B drugs. Achieving the goal of replacing physician purchasing of Part B drugs with such a complex system envisioned in the CAP program will likely require an incremental approach before implementing a full scale program.
- **Payment safeguards-** Fundamental additions and changes to the program are necessary to provide reasonable safeguards for prospective CAP vendors to ensure the expensive medications they are expected to supply have guarantees for payment.
- **Ability to obtain the lowest price-** Prices obtained under the CAP program should be exempt from best price calculations and prices should be updated frequently to reflect vendor purchasing costs.
- **Entity qualifications-** Bidding entities should meet basic requirements to qualify such as being a licensed pharmacy in good standing as well as employing licensed pharmacists.

from the determination of Medicaid best price and thereby also from ASP. Such a policy would bring the greatest savings to the Medicare program.

Physician Election Process (p.10765)

It is not clear in the NPRM how a vendor would be made aware that they have been selected by a physician. In order to ensure the physician is getting its drugs supplied in a timely fashion after selecting a vendor, notification of selection should be provided to the vendor directly in addition to CMS.

Vendor or Physician Education (p.10766)

We are concerned that the annual physician election (October 1 to November 15) as specified on p. 10766 may not be sufficient to conduct the necessary physician education. It is also not clear who is responsible for what in carrying out this process. Also, consistent with our comments above related to timely payment, PCMA urges that there be clear lines of communication created between the CAP carriers and vendors, so that vendors are informed on a timely basis as to when claims have not been filed within the recommended 14-day period.

Beneficiary Education (p.10767)

The NPRM proposes that CMS will develop a fact sheet on CAP that physicians may provide to beneficiaries that explains the CAP program and their responsibility for paying cost-sharing, as appropriate, to the CAP vendor. The preamble also indicates that information will be included in the Medicare & You Handbook, the Medicare website and will be available through the 1-800-Medicare helpline. We do not believe, given that CAP represents such a significant change in policy, that it is sufficient to explain the program in these general Medicare educational materials or leave it to the discretion of the physician as to providing a fact sheet. We believe it is important that Medicare patients be provided with specific information from CMS and a notice or fact sheet by the physician before or at the time of drug administration that explains the CAP program and also specifically identifies the drug(s) to be administered and the CAP vendor(s) involved. Also, we want to ensure that CAP vendors are not required to educate beneficiaries directly, since this is outside the capacity and roll of the CAP vendor.

Sincerely,

Mark Merritt
President and CEO

Categories of Drugs to be Included under the CAP (p.10749)

The statute (section 1847B(a)(1)(B) of the SSA) gives CMS the authority to phase-in categories of Part B drugs that would be offered under CAP. CMS outlines three major options in the proposed rule for the types of Part B drugs that would be included in the CAP program for its initial implementation for 2006.

We recommend that CMS limit CAP to a smaller set of drugs than all Part B drugs administered incident to a physician's specialty. Given the unique design of CAP and the fact that complex systems will need to be tested, we believe that a phased-in approach will allow for a smoother implementation. Moreover, new relationships have to be established (for example, between vendors and the CAP carrier, local carriers and the CAP carrier, and vendors and beneficiaries.) For all concerned, it may be easier to begin implementation with a smaller set of drugs than all drugs administered incident to a physician's service. We caution, however, that if the scope of drugs is too limited, that may discourage some potential entities from bidding to be contracting vendors and may also provide less incentive for physicians to enroll in the program.

Competitive Acquisition Areas (p.10752)

The Secretary is charged by law with establishing competitive acquisition areas (CAA) within which vendors will bid for contracts to supply Part B drugs. The program may be phased-in in only one or certain areas. CMS has invited comment on three options.

PCMA recommends that the Secretary establish a small number of large multi-state competitive acquisition areas (CAAs) based on existing markets within which vendors will bid for contracts to supply Part B drugs. We believe that a modest number of large regions best facilitates a competitive market for Part B drugs. We believe that a single national area would limit the number of vendors willing to participate in the CAP.

Claims Processing Overview (p. 10754)

The members of PCMA are in an especially strong position to comment on the proposed system for claims processing under the CAP. Our members have a long and successful track record of administering cost effective pharmacy programs, including specialty pharmacies, for employers, health plans, and governmental entities.

In the preamble to the NPRM, (p. 10748), CMS indicates that among the reasons for establishing the CAP approach to providing Part B covered drugs is to reduce the financial burden on physicians of the risk of non-payment for drugs, including the burden of collecting patient coinsurance. Under CAP, this financial burden is not only transferred to the CAP vendors, but a unique situation is established where payment to the vendor is conditioned upon the action of a third party, the physician. The proposed regulations would require that the vendor not be paid by Medicare, and not be allowed to bill the patient for cost-sharing, until the physician claim for administration has been approved and paid by Medicare. Part B covered drugs are often expensive, and the

vendors should not be required to supply product and then not receive any payment for months due to circumstances outside their control. The proposed system for claims processing would impose additional financial risk on the CAP vendors which may be great enough to discourage vendor participation in CAP.

Accordingly, we suggest that the regulations be amended as follows to help assure that CAP vendors receive timely and appropriate payments for Part B covered drugs provided for Medicare beneficiaries:

1. We strongly urge that, as part of their CAP participation agreement, physicians be required to submit their claims for administration services to carriers for Part B drugs within 14 calendar days of the anticipated date of drug administration. Should the physician fail to submit the claim within this time period, the CAP vendor should be permitted to bill the physician for reimbursement. The 14-day requirement should apply regardless of whether the physician has actually administered the drug. If, for example, the physician ordered the drug for a patient and administration failed to occur because the patient did not show up as scheduled, the vendor should still be permitted to bill the physician for the drug. From the vendor's perspective, once the drug is sent to the physician, the drug becomes the property of the physician. The vendor's adequate cash flow depends upon the vendor receiving prompt payment. If the drug is not administered, and consistent with safe drug practices, the physician may then retain the drug in his or her inventory to be administered to a future patient. In no instance in which the vendor has satisfactorily sent the ordered drug to the physician should the vendor be left holding the risk for non-payment because the drug was not administered or because the physician fails to submit a bill for the drug's administration.

2. Comment was requested on the proposed procedure for allowing physicians to use drugs from their office supply and then re-supply with product from the CAP vendor in emergency cases where there is not sufficient time to order the drug through the regular process. (p. 10755). We are concerned that "emergency" be defined narrowly and apply to the needs of the patient so that the process specified by CMS in this section is used appropriately and infrequently. We also note that there may be occasions when the drugs used by physicians from their own supply for emergency situations are multisource drugs. As specified in the law, in the case of multiple source drugs, a vendor only has to provide one competitively biddable drug within each billing and payment code (i.e., HCPCS code) within each category (for each competitive acquisition area). It follows that in instances where the physician seeks to replace a drug that was administered to a patient on an emergency basis that the CAP vendor should be permitted to replenish the physician's inventory with the drug within that HCPCS code which is the basis for the vendor's bid. This will not necessarily be the same drug (i.e., same NDC code) as was used from the physician's inventory. As noted above, the physician should in this instance also be required to submit the claim on a timely basis (within 14 days) so that the vendor can seek reimbursement.

3. CMS has proposed to allow physicians to opt out of their CAP agreement, obtain drugs, and bill Medicare directly under the ASP methodology in "furnish as written" (FAW) cases when a specific formulation of a drug, or a specific NDC for a multi-source drug is specified and the vendor has not been contracted to provide that formulation or the specific NDC. We believe that if this approach is included in the final regulation, it could lead to gaming on the part of physicians and manufacturers, allowing physicians to opt out of their CAP agreements when financially advantageous. We suggest an alternative. In such cases, the physician should first be required to order such products from their CAP vendor for that drug category. The vendor would then have the option of providing the formulation or obtaining the product with the specific NDC number and being paid by Medicare based on the ASP price rather than the CAP price. Another alternative would be for the vendor to be paid based on the CAP price but to have the option to decline to supply the specified formulation or specific NDC drug. Only if the vendor declined to supply the drug could the physician opt out of the CAP agreement for this particular service and be paid directly by Medicare based on ASP as described in the proposed rule. A third alternative might be to follow the NPRM proposal but to reimburse the physician based on ASP +0% rather than ASP + 6. We do not believe that simply having Medicare carriers conduct post payment reviews would be sufficient to prevent abuse of this "FAW" provision.

4. CMS has asked for comment on whether physicians should be allowed to choose a CAP vendor by category, or whether they should be required to obtain all categories of drugs that a particular vendor has contracted with CMS to provide. We believe that a physician should make their choice by vendor, receiving all their drugs from that one vendor, which has submitted a winning bid in all the relevant categories in CAP. This would lessen administrative burden for the physician so they would not have to manage potentially multiple vendors for each drug category.

5. CMS proposes (p.10755) to require physicians to agree to file claims for drug administration within 14 calendar days of the date of service unless there are extenuating circumstances. As noted above, we strongly support a 14-day requirement from the *anticipated* date of administration. We also do not believe a need exists to provide an exception for extenuating circumstances. Any such exception would be difficult to administer, potentially requiring a process of appeal or review, and be subject to gaming. In addition, we believe that a penalty should be imposed on a physician who repeatedly fails to file the claim within the required 14 calendar days. Should the physician fail to submit the claim, we believe that the physician should be required to pay the vendor directly if the vendor chooses to bill the physician. If, upon receipt of the bill, the physician fails to pay the vendor, the vendor should have the right to collect payment with interest from the government and the government would assume responsibility to collect from the physician. If the physician continues to fail to make payment, the vendor should have the right to suspend future delivery of Part B drugs to the physician.

6. CAP vendors will be in a difficult position regarding collecting patient cost-sharing because their only relationship with the patient comes at the point in the process when they send the patient a bill for the coinsurance. Consequently, we strongly support the CMS proposal (p. 10756) to require that the patient's supplementary insurance information and Medicaid eligibility information, as applicable, be provided by the physician on the order. We also urge that in the case of patients who have neither Medicaid nor supplementary insurance, the physician be required to include on the order the patient's credit card or debit card information if the physician uses this means of collecting the patient coinsurance for the physician's services.

7 & 8. The NPRM describes proposed policies for the handling of drug inventories by physicians participating in CAP and for situations where a drug has been ordered but not administered by the physician. As we understand the NPRM, each drug that is supplied would be given a unique identifier that is mapped to the patient and would follow the course of the drug to administration. This number would be indicated on the claims form that would be sent by the physician to the carrier and included through the adjudication of the claim. So long as the physician used this number to track and inventory the drug, we believe that separate storage is not necessary.

9. In situations where the drug is ordered but not administered, CMS is proposing that the physician be permitted to keep the drug in his or her inventory to use for another patient at a later time. CMS further proposes that when the time arose, the physician would order the drug from the vendor but indicate on the order that the drug need not be shipped because it was already in the physician's inventory. PCMA does not support this policy because the vendor loses control of the drug and cannot be responsible for its safety once it has been shipped to the physician. As an alternative, PCMA recommends that once the drug is ordered from the vendor, the drug would be given the unique identifier described above and supplied to the physician. The physician normally would be required to submit the claim for the drug with that unique code within 14 days of the date on which it is scheduled to be administered. If, however, the drug is not administered, the physician cannot submit a claim for administration of the drug and the vendor will not be reimbursed by Medicare. In this case, the vendor could bill the physician for the drug and the physician would be liable for payment. As noted above, consistent with safe drug practices, the doctor could keep the drug in his or her inventory and could administer it to another patient.

10. A potential problem exists relative to local coverage determinations. Under the CAP system, the physician has the responsibility of determining whether the drug will be covered. Should the physician fail to check for coverage, the vendor would never receive Medicare payment for a non-covered drug that was ordered and administered and would not be able to bill the patient. (P.10756-57) In cases where it is unclear if a drug will be covered, the Medicare program requires that physicians provide beneficiaries with an advance beneficiary notice (ABN) informing the patient that the service or item may not be covered and get the patient's consent to pay for the service should it be denied. If a signed ABN is not obtained, the patient is not financially liable. We suggest that the final regulations contain two provisions related to ABNs to protect the CAP vendors in cases

where coverage is not clear. First, physicians should be required to obtain a separate signed ABN on behalf of the CAP vendor for the drug whenever such physicians obtain an ABN that addresses their own drug administration services. Second, the CAP vendor should be allowed to require a signed ABN (obtained by the physician on behalf of the vendor) in cases where it believes there may be an issue with Medicare coverage.

11. Along similar lines, we believe that CAP vendors as well as physicians should be protected by the limitation on liability (Section 1879 of the Social Security Act) that provides for Medicare payment in initial claims which are denied as not "reasonable and necessary" and where both the individual and the provider or other person did not know, or could not reasonably have been expected to know, that the claim would be denied. In these situations, payment should be made for both the physician administration services as well as to the CAP vendor for the drug. This protection will be especially important in the case of new drug products or new, off-label uses for existing drugs.

12. Another concern that we have also relates to local coverage determinations. This is the application of Least Costly Alternative (LCA) policy by local contractors. In these situations, a local contractor has determined that a particular more costly drug is not more effective than a less costly drug and, based on this determination, the contractor limits the payment amount to the amount that would be paid for the less costly drug. Many local contractors, for example, have applied LCA to Lupron. Under this policy, when a physician administers Lupron, the contractor limits the Medicare payment to what Medicare would pay for Zoladex. It is important that these processes not be in place since the drugs are not provided as part of a formulary nor are vendors looking at formulary management techniques. Vendors are simply providing access to the drugs that physicians are requesting. PCMA believes that the final CAP regulations should state clearly that the LCA cannot be applied to drugs supplied through the CAP program.

Dispute Resolution (p. 10757)

In general, we believe that the success of CAP largely depends on CMS playing the enforcement role and not entities that become CAP vendors. Consequently, should there be a need for enforcement, we urge that CMS set out clear guidelines and expectations of physicians and that any formal process have as short a timeframe from start to finish as possible.

More specifically, CMS has asked for comments (p. 10758) on the appropriate amount for a vendor's loss threshold at which time the vendor may ask the carrier to counsel a physician who is not complying with the timely claims filing requirement. As noted above (see "Claims Processing Overview") PCMA believes that CAP vendors should not be placed at financial risk as a result of the failure of physicians to submit claims on a timely basis. As proposed, the rule provides for no incentive for physicians to file their claims on a timely basis. Nor does the NPRM suggest much in the way of effective penalties, short of dropping a physician from the CAP program. Also, the proposed rule does not address the situation in which the physician cannot receive Medicare payment for the drug administration because it is included in the global payment for a surgical

service (and is related to the surgery). We believe that a more effective remedy would be to permit vendors to refuse to enroll (or to reenroll) a physician for cause based on past failures (e.g., not billing for administration of the drug, or not paying the vendor in instances where the vendor has billed the physician for the drug, as would be permitted under our earlier recommendations). In addition, an additional enforcement option is for CMS to have the authority to exclude that provider from the Medicare program.

Bidding Entity Qualifications (p. 10760)

PCMA urges that CMS adopt certain minimum standards for vendors, which reflect 'best practices' of the industry.

Vendors should be licensed pharmacies and have on staff licensed pharmacists that are in good standing in the states in which they operate. In addition, vendors should be required to maintain sufficient records of their activities, have experience and ability to conduct drug utilization management, and the ability to conduct patient counseling if needed. Also, vendors must be able to abide by Federal laws and regulations for appropriately disposing returned products to ensure the drugs are not put back into stock.

CAP Bidding Process—Evaluation and Selection (p. 10762)

1. The proposed regulation is not clear as to how the single price for each drug will be determined when it is a multiple source drug. Vendors are not required to bid on, or provide, all drugs within a HCPCS code, but instead must provide only one. We propose that for multiple source drugs, the same method of determining the single CAP price that is used for single source drugs be employed, except that the bid prices for all NDC codes applicable to the HCPCS would be used to determine the median.

2. The NPRM proposes that the single price for each drug will be adjusted in years two and three of the contracts based on cost information provided by the vendors to the Secretary. This would be done annually, in or around October, or more frequently in cases where a new drug has been introduced; the expiration of a drug patent, or a material shortage in a drug has caused a significant price increase. The preamble to the NPRM also requests comments on an appropriate threshold change that would warrant the adjustment in price, and suggests 5 percent as an example (p.10764). We do not support the concept of a threshold but suggest instead that any price change be reflected in the payment update. We also recommend that the update be made on a quarterly basis. Changes in drug prices are more likely to be increases than decreases, and a small increase in price for an expensive drug or one that has significant volume can have sizable financial implications for a vendor. If a threshold is adopted, however, we recommend that it be minimal (e.g., 0.5 percent).

3. The regulation is silent on whether CAP bid prices would be excluded from Medicaid best price and, consequently also ASP reporting. In order for vendors to be able to obtain the best prices from manufacturers for CAP, the bid prices should be explicitly excluded

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National Kidney Foundation®

Making Lives Better

APR 26 2005

April 20, 2005

Department of Health and Human Services
Attention: CMS-1325-P
PO Box 8010
Baltimore, MD 21244-8010

Dear Sir or Madam:

On behalf of the 50,000 patients and professional members of the National Kidney Foundation, I am submitting these comments on the CMS Proposed Rule for the Competitive Acquisition of Outpatient Drugs and Biologicals under Part B, ("CAP" Program), CMS-1325-P, as published in the ***Federal Register*** on March 4, 2005.

We have serious concerns about the design of the CAP program that is described in the Proposed Rule. As we understand it, the CAP program applies to injectable or intravenous drugs that are reimbursable under Part B as incident to a physician's service. Beginning January 1, 2006, as an alternative to purchasing drugs from manufacturers or wholesalers, physicians will be given the option of obtaining these drugs through a CAP vendor who will bill Medicare for these drugs, as well as collect co-payments from Medicare beneficiaries. As stated in the Proposed Rule, the CAP program is designed to reduce the financial burden for physicians. Nevertheless, because of the regional bidding envisioned in the Proposed Rule, it may be difficult to attract vendors to low-volume markets, thus minimizing one of the expected advantages of the new program. Furthermore, patient co-pay obligations would vary and could be higher in low-markets.

Secondly, Medicare beneficiaries should have access to all drugs in every category covered by Part B and their physicians should be able to prescribe the particular drug that they believe is most beneficial to their patients. On the other hand, section 414.906 (b) states that specific competitively biddable drugs may excluded from the CAP if the application of competitive bidding to these drugs—(1) is not likely to result in significant savings; or (2) is likely to have an adverse impact on access to such drugs. As a result, the CAP program looks like a formulary and there is no

precedent for formularies under Part B.

We continue to hope that the Final Rule for the competitive acquisition program will enhance rather than restrict patient access to care and trust that our concerns and the concerns of our patients will be reflected in that Final Rule.

Sincerely,

David G. Warnock, M.D.
President, National Kidney Foundation, Inc.
Professor and Director, Division of Nephrology
Department of Medicine
University of Alabama at Birmingham

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NAMI

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Missouri's Voice on Mental Illness

April 20, 2005

APR 2?

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS – 1325-P
P.O. Box 8010
Baltimore, MD 21244-8010

Dear Sir or Madam:

This is in response to the published opportunity for public comment in regard to proposed rules for the "Medicare Competitive Acquisition Program" (CAP) for Part B Medications. Notice appeared on March 4, 2005 in the Federal Register and comment may be made until April 27, 2005.

The medical treatment of psychiatric illness is truly unique. While brain research has produced a number of recent new discoveries and treatments, this field is still quite young. Brain research has yet to provide us with individual therapies that provide optimal response for the serious psychiatric illnesses. This is particularly true of treatments for psychosis.

Individual differences in brain structure, body chemistry, genetic factors, physical health, etc. make individualized treatment for psychiatric illness essential. It is common for physicians to try various medications and combinations to find just the right dosage and combinations to help a patient find and maintain stability.

We urge you to include psychiatric medications in the CAP program. Their inclusion would provide access to just the kind of treatment needed to foster long-term stability and recovery and reduce the expensive cycles of severe psychiatric symptoms and hospitalizations that often afflict people with mental illness.

More often than not, people with severe psychiatric illness will have multiple conditions (such as psychosis with anxiety disorder or psychosis with depression). We therefore urge you to create a category that includes treatments for diagnoses listed in the DSM-IV (revised).

Finally, continuity of therapy is critical in the effective treatment of psychiatric illness. Please make sure vendors have a simple, user-friendly process that responds quickly and reimburses promptly. Such a process should be adequately equipped to handle patient co-pays and remove any potential for interrupted medical therapy.

On behalf of our 3000 members and the thousands of person with mental illness and families we serve, I thank you for considering our comments.

Until there is a cure,

Cynthia R. Keele

Cynthia R. Keele
Executive Director

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Rec'd 4/21/05
L. Mill.

April 26, 2005

Dr. Mark McClellan
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1325-P
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1325-P

Dear Dr. McClellan:

CMS published Proposed Rule CMS-1325-P, "Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B" in the March 4, 2005 *Federal Register* (the "Proposed Rule.").[1] Our comments on the Proposed Rule follow. As requested, we have keyed our remarks to issue identifiers set forth in the proposal

CAP as a Voluntary Program: Inadequate Services Reimbursement

Issue Identifier: Overview of the CAP

In its implementation of the Medicare Modernization Act of 2003 (MMA), the Centers for Medicare and Medicaid Services (CMS) has sought to more adequately cover the labor, supply, pharmacy, and other costs incurred in the administration of cancer-fighting drugs. Among the steps taken is the adoption of G codes to cover drug administration services and the creation of a demonstration project for 2005 that provided additional reimbursement.

As a result, 2005 Medicare reimbursement for cancer care services is considerably higher than pre-MMA rates. However, total reimbursement will drop dramatically on January 1, 2006, when the demonstration project is scheduled to end and the drug administration transitional factor will be zeroed out.

As the attached detailed analyses illustrate, community oncology is facing a substantial reimbursement shortfall beginning January 1, 2006, unless corrective regulatory or legislative action is taken. In fact, it has been calculated that the impact of these changes will translate into a $1,060.10 underpayment for drug administration services per Medicare beneficiary, assuming that half of all co-payment obligations is collected. On an aggregate basis, this would result in a $620.9 million loss in 2006. Put another way, 2006 Medicare reimbursement for patient care services will cover only an estimated 50.1% of drug administration costs. Just as troubling, even if the projected 4.3 percent fee schedule cut is replaced with a 1 percent increase and if the 2005 symptom management demonstration project funding is extended through 2006, the net Medicare underpayment on services remains – totaling an estimated $350.3 million or $598.01 per beneficiary.

This problem is a key factor in the implementation of the Competitive Acquisition Program (CAP) in 2006. Under CAP, middlemen vendors will furnish drugs to physicians who opt to participate in the CAP model. The vendors will be responsible for billing Medicare for the drugs, and the physicians will receive reimbursement only for drug administration services.

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[1] 70 *Fed. Reg.* 10745 (March 4, 2005).

CMS expects CAP to appeal to those physicians "who do not want to be in the drug procurement and drug coinsurance collection business" [70 *Fed. Reg.* 10750]. Indeed, statements made by CMS and CAP's Congressional authors all reinforce the notion that CAP is intended to be an option that physicians may choose to adopt in place of the current buy-and-bill model. According to the MMA Conference Report produced by Congress, "Conferees intend this choice to be completely voluntary on behalf of the physicians" [H. R. Conf. Rep. No. 108-391, 108th Cong., 1st Sess. 593 (2003)].

And yet, it is possible that neither CMS nor Congress has recognized that the viability of these two choices turns on the adequacy of reimbursement for drug administration services. Unless changes are made, many oncologists will face a loss under the buy-and-bill model, a loss that will be even *greater* should they opt to participate in CAP. This is because the only reimbursement they will receive under CAP is payment for drug administration services – which will fall well below the cost of providing drug administration services.

In light of the reimbursement shortfall that looms on January 1, 2006, many cancer care specialists will face a very different choice than the one that Congress intended: continue to offer cancer care services to seniors (under buy-and-bill or CAP) and incur a significant net loss...or discontinue offering chemotherapy services to Medicare beneficiaries altogether. Sadly, both approaches threaten the community cancer care services on which millions of Americans now depend.

Congress has clearly stated its intent that patient access to community cancer care must be preserved because it is the source of convenient, cost-effective care for more than 4-out-of-5 American cancer patients. If CMS intends to abide by this intent, it must take additional steps to align Medicare reimbursement with the cost of drug administration services.

Because the level of needed fee schedule restructuring is significant, CMS may be unable to solve this pending crisis before the 2006 Physician Fee Schedule must be published. As a result, we urge CMS to extend the quality demonstration while it works to match drug administration cost and payments. Otherwise, both the CAP and the ASP models will be doomed to failure and many Medicare cancer patients likely will be forced back to hospitals for chemotherapy.

Potential for Increased Patient Costs

Issue Identifier: Claims Processing Overview

As US Oncology has expressed frequently in the past, we are deeply concerned that the proposed rule's delivery standards could pose a significant risk of increased financial and clinical costs to cancer patients. Today, cancer care practices routinely maintain a drug inventory to meet their patients' treatment needs. This has enabled practices to accommodate changes in patients' treatment plans without requiring the patient to return for therapy on another day. Under CAP, however, this level of service could be difficult if not impossible to maintain.

If chemotherapy sessions must be rescheduled to wait for the delivery of the drug(s) that patients need, they will face additional coinsurance obligations for the repeat physician services. In addition, patients will face other financial burdens in the form of higher transportation costs and additional missed time from work. This situation may also mean missed work time and reduced productivity for family members and other caregivers who must bring beneficiaries to the rescheduled treatment sessions.

We recognize that Social Security Act 1847B(b)(5) and the proposed rule permit physicians to receive replacement product from their CAP vendors for drugs taken from the physician's inventory. Even if CAP physicians had a sufficient inventory to draw from, this option appears too narrowly tailored to save most patients from having to undertake a return trip and bear the cost of an additional coinsurance payment. Specifically, the use of the replacement program is limited to situations where the physician builds a record to demonstrate all of the following to the local carrier: (1) the drugs were required immediately, (2) the physician could not have anticipated the patient's need for the drugs, (3) the CAP vendor could not deliver the drugs in a timely manner, and (4) the drugs were administered in an emergency situation.

There are a few glaring problems with the inventory replacement option. First, neither the statute nor the proposed rule defines "emergency." Moreover, neither the proposed rule nor the preamble discussion explains what a physician would have to show to justify immediate need or how the local carrier will assess whether the physician could have anticipated the patient's drug needs sufficiently far in advance to permit delivery via the CAP vendor. Aside from the risk that the claim for replacement drug will be denied by the local carrier, the administrative burden of building this record may discourage many physicians from using the inventory replacement option. The inventory replacement option also raises the question about whether commercial insurers are being asked to subsidize a portion of the drug costs for Medicare beneficiaries in CAP, since Medicare would not be paying a physician for the ordering, financing, inventorying and handling costs associated with drugs borrowed from the practice's inventory.

We are even more concerned about what this option could mean for patients, since it is not at all clear that oncology practices will be able to maintain full inventories after the implementation of CAP. Depending on their patient bases, the range of drugs that some practices would need for Medicare beneficiaries may not be the same as the drug inventory that the practice would stock for commercial patients. Moreover, if CAP encourages the proliferation of mandatory vendor imposition (MVI) programs among commercial carriers, it is likely that some practices may stop maintaining drug inventories altogether.

In sum, patients may be forced to pay both a financial and clinical price for treatment disruptions due to CAP, potentially exposing them to medical complications and increased emergency hospitalizations in addition to repeat visits and higher cost-sharing obligations.

Burdens on Physicians

Issue Identifier: Claims Processing Overview
Dispute Resolution

According to the preamble to the Proposed Rule, in CMS's view, CAP will not significantly increase the administrative burden that physicians currently face under the buy-and-bill model. Therefore, CMS has concluded that the payment for clerical and inventory management services associated with buying and billing drugs under the ASP system that is bundled into the drug administration codes should be adequate to cover the practice expenses which physicians will occur because of a CAP selection. For a number of reasons, we strongly disagree.

First, CMS is counting on the fact that physicians participating in CAP will continue ordering drugs for their non-Medicare patients through the normal distribution channels currently used by their practices. In fact, CMS expects CAP physicians to draw on the drug inventories that they maintain to treat Medicare beneficiaries in an emergency or when the beneficiary needs a particular drug that is not available through the physician's CAP vendor.

Although the volume of drugs that a physician participating in CAP would need to order, handle, store, bill, and pay for would be reduced, the administrative cost of managing a drug inventory would not be eliminated nor, because of economies of scale, necessarily reduced proportionally based on the reduction in drug volume attributable to Medicare patients.

Second, practices would have to implement and operate a second, separate ordering process for CAP drugs. That system would require the transmission of patient-specific drug orders that include demographic and clinical information. The ordering system under the buy-and-bill model is much simpler because aggregate orders based on overall practice usage trends are placed with wholesalers. Buy-and-bill ordering does not involve the review of individual patient charts nor does it require input of substantial amounts of data for each vial of drug requested from the wholesaler. Further, the number of individual orders under the CAP model will be substantially higher than the number under the traditional buy-and-bill model. Depending on how CAP categories are defined, physicians could even find that they have to order from and deal with multiple CAP vendors. Physicians also may have to revamp their appointment scheduling operations to accommodate CAP delivery times.

Third, because CMS believes that physicians will be able to avoid maintaining patient-specific inventories of CAP drugs that are physically separate from each other and from inventory held for the treatment of non-Medicare patients, it assumes that they also will avoid the added costs of the extra storage space, new refrigeration equipment and the special handling that such separate inventories would entail. As we discussed in our comments above on Product Integrity considerations keyed to Issue Identifiers "Contracting Process – Quality and Product Integrity Aspects" and "Claims Processing Overview," state pharmacy laws applicable to CAP vendors may prevent physicians from applying the type of consolidated inventory management techniques that CMS contemplates.

Unlike CMS, we expect CAP to increase the demands on oncology practices for pharmacy management services. Changes in individual treatment plans will have to be closely monitored so that new prescriptions can be sent to the vendor in timely fashion. The job of ensuring that drugs are given to the right patient and that patient-specific drug supplies provided in multi-dose vials have not expired or passed stability deadlines before the entire vial is used will be more complicated because the time that any particular multi-dose vial must be maintained and monitored will increase. The increases in complexity of required pharmacy management services inevitably will increase the risk of medication errors unless new clinical controls and communication processes are developed and implemented.

We are particularly concerned about any potential increase in costs associated with drug handling because a study of pharmacy costs in oncology practices recently completed by the University of Utah on behalf of the Global Access Project suggests that the average cost of these services per dose of chemotherapy preparation is already $36.03.[2] Moreover, CMS staff has never been able to establish to our satisfaction that the current level of pharmacy services costs is captured in the practice expense component of payments for drug administration services.

Fourth, to the extent that state pharmacy laws will require patient-specific shipments and inventories under CAP, the model likely will increase hazardous waste disposal costs substantially. Again, as we discussed in our comments above on Product Integrity

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[2] "Documentation of Pharmacy Cost in the Preparation of Chemotherapy Infusions in Academic and Community-Based Oncology Practices," prepared by University of Utah Pharmacotherapy Outcomes Research Center, and submitted to the Lewin Group on behalf of the National Patient Advocate Foundation and the Global Access Project, Feb. 9, 2005. Copies of the study have been presented to CMS, MedPAC, the Congressional Committees with jurisdiction over CMS, and the Administration. Please contact the National Patient Advocate Foundation at 202-347-8009 for additional copies.

Considerations keyed to Issue Identifiers "Contracting Process – Quality and Product Integrity Aspects" and "Claims Processing Overview," state pharmacy laws may block CMS's plans for the redirection, in the physician's office, of unused drug dispensed for one patient to another patient, even if the original patient no longer needs or can receive the drug and the second patient needs and can receive it. Since returning the drug to the CAP vendor's inventory poses significant safety concerns, especially if the unused drug is in a multi-dose vial that has already been penetrated to remove part of its content, drug dispensed for a specific patient must be discarded if the patient cannot use the drug for any reason. Furthermore, waste handling costs will be amplified under CAP because of the increased likelihood that a drug designated for a particular patient will pass its expiration or stability deadline before all of the vial can be finished. As a result, we anticipate that the number of vials of drug that will have to be discarded under CAP will soar. We also are concerned that total waste quantities, particularly for larger practices, could quickly exceed levels allowable for routine disposal, thereby adding even greater costs.

Fifth, when physicians sign a CAP Election Agreement, they must agree to file Medicare claims for drug administration services within 14 days of the delivery of the drug administration service. This requirement obviously would involve an increased administrative burden on physicians since the Proposed Rule acknowledges that only about 75% of claims currently are filed within this timeframe.[3] Further, claims for drug administration under CAP would have to carry the prescription number for the particular dose of product administered as well as all of the data elements, including the HCPCS code of the drug administered, that go on claims now filed under the buy-and-bill model. To accommodate this billing change, physicians will likely have to modify their "superbills," upgrade their claims processing software, and develop new systems capability for communicating prescriptions to CAP vendors electronically. In addition, the simple reality is that each data element on a Medicare claim takes time to collect, input, and track down when someone forgets to complete a record in full.

CMS has proposed permitting exceptions to the 14-day claims filing requirement in "extenuating circumstances," but, without making any suggestions, it has merely requested public input on what such appropriate extenuating circumstances might be. We presume that CMS has already thought through the problem the 14-day timeline poses when Medicare is the secondary payer. We also hope that it will make provisions for *force majeure* events.

We assume the desire to ensure prompt payment for CAP vendors underlies the requirement for the 14-day billing turn-around. We are troubled, however, that CMS also would consider making partial payments to a CAP vendor, presumably to save the vendor the time value of money, in a Proposed Rule that provides absolutely no relieve to physicians for the added costs they will bear if they select the CAP model. Moreover, we cannot help but believe that a partial payment methodology will enhance the already significant administrative burden of CAP on physicians. Physicians have never received partial payments for drugs billed to Medicare and they will not receive such payments if they continue providing drugs under Social Security Act §1847A.

Furthermore, Medicare does not offer partial payments to IV and respiratory pharmacies that supply drugs used with pumps and nebulizers. These pharmacies bill for the drugs they furnish through the DMERCs under the DME benefit. Even though the carriers must, at times, match up drug and equipment claims coming from two different organizations to make coverage decisions and process payments, these specialty pharmacies do not receive partial payments. We see no reason why CAP vendors should be treated differently.

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[3] 70 *Fed. Reg.* 10755.

We also are concerned about the potential impact of partial payments if the vendors are permitted to bill beneficiaries partial coinsurance amounts. Such a practice would present significant program integrity issues with respect to the return of funds improperly collected. Although partial payments are not without precedent since Medicare does make them under the home health prospective payment system, it is significant that the home health benefit has never carried a beneficiary coinsurance obligation.

Sixth, a decision to participate in CAP would strip physicians of the ability to make a cost-benefit decision about the value of appealing a claim denial for drug administration services. This change in practice will take on added significance – both in terms of administrative burden and cost – once the new Medicare claims appeal procedures are implemented, because those rules generally require physicians to submit all of the evidence needed to support the appeal when the initial request for a carrier redetermination is filed.[4] Although we recognize that this requirement is intended to speed up the claims appeal process and will apply to any appeal of a physician service that a doctor decides to take, it undoubtedly will increase the administrative burden of preparing mandatory appeals under CAP.

Seventh, if physicians use the drug replacement provisions of CAP, they will be expected to notify the CAP vendor about the change in the patient's treatment plan and negotiate redirection (or presumably destruction if redirection is not feasible) of the unused drug. In addition, they will be expected to maintain documentation showing that that all 42 CFR §414.906(e) requirements were met. Aside from the burden of ensuring that their medical records satisfy this new documentation requirement, physicians will be subject to post-payment review and recoupments if the local carrier concludes that the records do not justify resupply through the CAP vendor. We cannot help but note that the carrier will be tasked with deciding whether the physician administered the drug in question in an "emergency" situation even though the Proposed Rule provides no definition of this term. Moreover, we presume that physicians who receive post-payment claims denials will be subject to the mandatory CAP appeal requirements.

Eighth, physicians that write "furnish as written" orders when the drug they wish to prescribe is not available through their CAP vendor will have to maintain documentation supporting why the particular drug selected was medically necessary. Although physicians always must be prepared to support the medical necessity of their orders, the decision has not historically turned on a comparison of the clinical appropriateness of one drug within a HCPCS code with that of any another. As a result, the "furnish as written" procedures create yet another new CAP-specific documentation requirement. As is the case with replacement drugs, claims for "furnish as written" orders will be subject to post-payment reviews and will, if denied, trigger an obligation to appeal under CAP.

Ninth, disputes between physicians and CAP vendors will inevitably arise. Some physicians will have complaints about quality or service. Some vendors will be concerned about slow claims filing or excessive levels of claims denials. The Proposed Rule establishes dispute resolution procedures to deal with these situations. Although these procedures are undoubtedly necessary, they will impose another new administrative burden on CAP physicians when disputes must be addressed and resolved. With respect to the idea of establishing a threshold amount that would trigger intervention by the designated carrier in a dispute over an excessive level of claims denials, we note that the threshold should not be purely monetary but rather should consider number of claims as well to deal with differences in the costs of particular therapies. Otherwise, physicians could find themselves facing the administrative burden of a dispute resolution process over a handful of claims denials of drugs that happen to be very expensive.

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[4] 70 *Fed. Reg.* 11419 (March 8, 2005). (The new rules become effective January 6, 2006 for physicians, essentially simultaneously with the implementation of CAP.)

Given the management, inventory control, drug preparation, paperwork, integrity assurance, and other necessary new or enhanced functions that will face physicians selecting CAP, we urge CMS to establish a new HCPCS code for pharmacy management services valued to compensate physicians, on a patient-by-patient basis, for the staff time and effort required to communicate and coordinate care plans with a CAP vendor, complete CAP-required paperwork, and provide follow-up tracking and enhanced safety systems to prevent medication errors.

To address the hazardous waste disposal problem likely to result under CAP, CMS should require each CAP vendor to subcontract with properly licensed and permitted hazardous waste haulers and disposers to pick up from physicians discarded drugs dispensed by the vendor and to destroy those drugs in accordance with applicable federal, state, and local laws. Mandating a subcontract arrangement would protect against discarded dispensed drugs being returned to inventory and resold in contravention of state pharmacy laws. Such an arrangement is permissible under Social Security Act §1847B(b)(6) despite the fact that the statute expressly prohibits CAP vendors from including "any costs related to . . . wastage" in their bid prices because nothing in the Social Security Act precludes CMS from making the cost of a CAP vendor's hazardous waste disposal subcontract a pass-through cost that would be reimbursed separate and apart from payments for dispensed drugs. This approach has the advantage of limiting disposal costs to only those drugs actually wasted. To control waste disposal costs further, CMS could build performance measures into CAP vendor contracts to encourage them to develop systems for minimizing the volume of hazardous waste associated with their programs and couple those measures with penalties for sub-par or incentives for above-par performance.

CAP Must Be a Physician-Specific Program, Not a Practice-Specific Program

Issue Identifier: Physician Election Process

Social Security Act §1847B(a)(1)(A)(ii) states that *each physician* may select between the buy-and-bill model and the CAP model on an annual basis. Further, §1847B(a)(1)(A)(iii) required that *each physician* selecting the CAP option be given the opportunity to pick the CAP vendor of his or her choice. CMS's apparent decision to make the choice between the buy-and-bill model and the CAP model a group practice decision[5] rather than a physician-specific decision is contrary to the plain language of the statute. It is also inconsistent with Congress' stated intent that the choice of CAP should, as stated in the Conference Report, "be completely voluntary on behalf of *the* physician."[6]

CMS has justified its decision to make the choice between buy-and-bill and CAP a group practice choice by saying that Social Security Act §1847B(a)(5)(A) "requires that we coordinate the physician's election to participate in the CAP with the Medicare Participating Physician Process described in section 1842(h) of the Act."[7] That is not quite right. What §1847B(a)(5)(A)(ii) actually requires is that "[t]he *selection of a [CAP] contractor* . . . shall be coordinated with agreements entered into under section 1842(h) [which authorizes the Medicare Participating Physician Process]" (emphasis added). Instead of reading the statutory requirement to "coordinate" the CAP vendor selection process with the Medicare Participating Physician Process simply as a directive to minimize paperwork by aligning the two selection processes in time and utilizing the same form for both, CMS has taken a

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5 70 *Fed. Reg.* 10766 ("We propose that, consistent with the Medicare Participating Physician Process, if members of a group practice elect to participate in the CAP, the entire practice would participate. . . . We propose that when a physician bills as a member of a group using the group PIN, he or she must follow the group's election to participate or not to participate in the CAP").

6 H. R. Conf. Rep. No. 108-391, 108th Cong., 1st Sess. 593 (2003)

7 70 *Fed. Reg.* 10765.

completely different tact. It has separated the two selection processes in time but chosen otherwise to model the CAP selection process after the Medicare Participating Physician Process. In so doing, it has converted the CAP selection process into a group practice decision and effectively eliminated the option of individual physician decision-making about CAP required by the statute and intended by Congress.

In some instances, physicians in group practices will be unable to come to agreement about the choice between the buy-and-bill model and the CAP model. On the one hand, some physicians feel strongly about the risks to product integrity under CAP because of problems with counterfeit drugs experienced under the MVI programs required by certain commercial insurers. Others are concerned about the potential impact on beneficiary access if CAP vendors are permitted to "cut off" patients who fail to make timely coinsurance payments. Still others simply do not see how they can afford the increased administrative burden and increased drug-handling costs expected under CAP. On the other hand, other physicians may see CAP in the way CMS has characterized it: "an alternative to physicians who d[o] not want to be in the drug purchasing business and d[o] not want to have to collect coinsurance on drugs."[8]

These types of concerns promise to be more difficult to resolve than are disagreements about participating physician status and we could envision situations where the CAP question could cause practices to dissolve.

CMS has offered an unsatisfactory "solution" to address the statutory requirement for individual physician choice: if the "physician in the group practice also has a solo practice, he or she may make a different determination to participate or not to participate in the CAP when using his or her individual PIN."[9] In fact, this seems to invite groups that cannot agree on the CAP issue to break apart to preserve each camp's ability to qualify as a group practice under the Stark Law. Although the provision of "incident to" drugs furnished by a CAP vendor presumably will not trigger the Stark Law since a practice will have no financial stake in the outpatient prescription drugs, many group practices rely on the in-office ancillary service exception for purposes beyond drug treatment and would have legitimate concerns about the implications of a partial break-away of group members under the "substantially all test" used to define group practices.

We recognize that CMS's claims processing systems are set up based on group numbers and that carriers may need to implement system changes to deal with individual choice. And yet, we also recognize that the statute, the Conference Report, and even statements made by the CMS Administrator all share one crucial theme: participation in CAP will be a physician's completely voluntary choice. Denying the right of individual choice simply to avoid system upgrades is unfounded and unacceptable.

Product Integrity Considerations

Issue Identifiers: Contracting Process – Quality and Product Integrity Aspects
Claims Processing Overview

The World Health Organization estimates that 6% of all drugs distributed in the world are counterfeit, and a recent article published in *Plos Medicine*[10] more than doubles that estimate. We are aware of oncology practices that have received counterfeit products from specialty pharmacies retained by managed care organizations to provide chemotherapy and

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8 70 *Fed Reg.* 10749.

9 70 *Fed. Reg,* 10766.

10 "One in Seven Drugs Fake Worldwide, Claims Report," *in-Pharma Thecnologist.com,* www.in-pharmatechnologist.com/news/printNewsBis.asp?id=52680.

support drugs to enrollees with cancer. Since most counterfeit drugs in the United States enter the chain of commerce through the secondary market, we applaud Congress' decision to require CAP vendors to acquire all of their drugs directly from the manufacturer or from a wholesaler that buys direct.[11]

We expect the regulations implementing the direct purchasing requirement to go a long way toward preventing the distribution of counterfeit products by CAP vendors. We note, however, that product integrity is about more that blocking the distribution of counterfeit goods. That is why we are concerned that the Proposed Rule's provisions could jeopardize product integrity and violate state licensing laws. We fear that some of the procedures that CMS sketches out in the preamble to the Proposed Rule related to the management of CAP drugs within a physician practice and the redirection of unused CAP drugs from one patient to another have the potential to jeopardize product integrity. They also likely violate state licensing laws that will govern the operation of CAP vendors.

We suspect that CMS may not have thought through some of the licensing and product integrity issues that trouble us because it seems to have concluded that CAP vendors should be licensed as wholesalers, but not as pharmacies. The preamble to the Proposed Rule states that vendors must "comply with State licensing requirements and be in full compliance with any State or Federal requirements for *wholesale distributors* of drugs or biologicals in States where they furnish drugs for the CAP."[12] (emphasis added) Furthermore, the Competitive Acquisition Program (CAP) for Medicare Part B Drugs Drug Vendor Application[13] requires CAP applicants to attest to the fact that they and "any subcontractor or affiliate involved in CAP, will be in full compliance with State and Federal requirements for *wholesale distributors* of drugs in the entire geographic area where the organization furnishes drugs for the CAP."[14] (emphasis added). No such attestation about pharmacy licensing is required. Finally, the entire discussion of product integrity in the preamble focuses on wholesale distributors and the advice for preventing the distribution of counterfeit pharmaceuticals provided to them by the FDA and the Healthcare Distribution Management Association, the trade association for the national full-service wholesalers.[15]

We are convinced that CAP vendors must be licensed as pharmacies. The statute does not expressly define the class of trade of a CAP vendor and §1847B(b)(4)(C) could suggest that Congress viewed CAP vendors as wholesalers. And yet, Social Security Act §1847B(b)(6) seems to take a different position, stating that nothing in Social Security Act §1847B "shall be construed as waiving applicable State requirements relating to licensing of pharmacies."

We are convinced that CAP vendors must be licensed as pharmacies. We recognize that Social Security Act §1847B does not expressly define the class of trade of a CAP vendor and see how §1847B(b)(4)(C) could suggest that at least some CAP vendors were anticipated to be wholesalers. That section notes that "nothing in th[e] subparagraph [setting forth the requirement that CAP vendors must acquire all of their inventory either directly from the manufacturer or from a distributor that buys direct] shall be construed to relieve or exempt any contractor from the provisions of the Federal Food, Drug, and Cosmetic Act that relate to the wholesale distribution of prescription drugs." That said, Social Security Act §1847B(b)(6) seems to take a different position, stating that nothing in Social Security Act §1847B "shall be construed as waiving applicable State requirements relating to licensing of *pharmacies*." (emphasis added).

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11 Social Security Act §1847B(b)(4)(C).
12 70 *Fed. Reg.* 10759 (March 4, 2005).
13 *See* www.cms.hhs.gov/regulations/pra
14 *See* Part I (2)(D) of the Application.
15 70 *Fed. Reg.* 10759.

We submit that the best way to reconcile these two sections of Social Security Act §1847B is to conclude that §1847B(b)(6) takes precedence since it expressly states that, with respect to CAP vendors, nothing in all of §1847B supercedes state pharmacy laws, which in our view require CAP vendors to be licensed as pharmacies. The language in §1847B(B)(b)(4), on the other hand, can best be read as saying that the requirements to buy direct from the manufacturer or from a distributor that buys direct do not excuse CAP pharmacies from federal and state recordkeeping and operational requirements applicable to wholesalers when, as licensed pharmacies, they engage in wholesale distribution to support the drug replacement option included in the CAP proposed rule. This reading of §1847B(b)(4) is consistent with the fact that the Food, Drug and Cosmetic Act ("FDCA") includes "retail pharmacies that conduct wholesale distributions" within the definitions of "wholesaler" at 21 USC §§203.3(dd) and 205.3(g). The FDCA also defines "wholesale distribution" as "the distribution of prescription drugs to persons other than a consumer or patient" and states expressly that wholesale distribution does not include "the dispensing of a drug pursuant to a prescription." 21 USC §205.3(f)(6).

In our view, CAP vendors must be licensed as pharmacies because they will accept patient-specific written orders for prescription drugs from physicians,[16] assign prescription numbers to those orders,[17] interpret the orders, presumably making generic substitutions as appropriate and permissible under applicable State law,[18] and then transfer dispensed drugs to the prescribing physician for administration to the patient. Title to the drugs will not transfer to the physician, who will merely be acting as the patient's agent, but will remain with the CAP vendor until the drug is administered to the patient. The vendor will be responsible for billing Medicare and collecting coinsurance and deductibles from the beneficiary or the beneficiary's other third-party payer(s). This patient-specific transfer amounts to "dispensing" a drug under state pharmacy practice acts[19] and because CAP vendors dispense, they are practicing pharmacy[20] and must be licensed accordingly.

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16 CMS characterizes CAP drug orders as prescriptions in the preamble to the proposed rule. *See* 70 *Fed. Reg.* 10753 ("the physician submits a written order or prescription . . . to the vendor . . .").

17 "The drug vendor would generate the prescription number when it prepares the drug for shipping." 70 *Fed. Reg.* 10754.

18 "[W]e are proposing that vendors will not be required to provide every National Drug Code associated with a HCPCS code. . ."(70 *Fed Reg.* 10751) because, with respect to multi-source drugs, Social Security Act §1847B(b)(1) permits vendors to offer only one competitively biddable drug within each billing and payment code.

19 Throughout these comments, we have based our assessment of state pharmacy law on the laws and regulation in California, Florida, Illinois, New York, and Texas since approximately 40% of the country's Medicare beneficiaries live in these five states. In California, "'dispense' means the furnishing of drugs or devices upon a prescription from a physician . . . " (Cal. Bus. & Prof. Code § 402.4) and "'furnish' means to supply by any means, by sale or otherwise." (Cal. Bus. & Prof. Code § 4026). In Florida, "'Dispense' means the transfer of possession of one or more doses of a medicinal drug by a pharmacist to the ultimate consumer or her or his agent. As an element of dispensing, the pharmacist shall . . . interpret and assess the prescription order . . . and the pharmacist shall certify that the medicinal drug called for by the prescription is ready for transfer. . . . The administration shall not be considered dispensing." (Fla. Stat. Ann 465.003(6).) In Illinois, "'dispensing' means the delivery of drugs and medical devices, in accordance with applicable State and federal laws and regulations, to the patient or the patient's representative authorized to receive products, including the preparation, compounding, packaging, and labeling necessary for delivery, computer entry, and verification of medication orders and prescriptions. . . ." (225 ILC § 85/3(m)). In Texas, "'Dispense' means to prepare, package, compound, or label, in the course of professional practice, a prescription drug or device for delivery to an ultimate user or the user's agent under a practitioner's lawful order." (Tex. Occ. Code Ann. § 551.003(16)). The concept of dispensing is not defined in New York statutes or regulations governing pharmacists or pharmacies, but the state's controlled substance laws state that "Dispense means to deliver a controlled substance to an ultimate user or research subject by lawful means and includes the packaging, labeling, or compounding necessary to prepare the substance for such delivery." 14 NYCRR § 829.3(g).

20 With certain exceptions, Cal. Bus. & Prof. Code § 4051 makes it unlawful "for any person to manufacture, compound, furnish, sell, or dispense any dangerous drug or dangerous device, or to dispense or compound any prescription . ..unless he or she is a pharmacist." Fla. Stat. Ann. § 465.003(13) states the "'Practice of the profession of pharmacy' includes compounding, dispensing and consulting concerning contents, therapeutic values, and uses of any medicinal drug." Similarly, under Illinois law, the practice of pharmacy is defined as "compounding and dispensing of drugs and medical devices" (225 ILC § 85/3(d)), under New York law as "the preparing, compounding, preserving, or the dispensing of drugs, medicines and therapeutic devices on the basis of prescriptions or other legal authority (N.Y. Educ. § 6801), and under Texas law as, among other things, "being

Since CAP vendors must operate as licensed pharmacies, some of the operational aspects of CAP contemplated by CMS seem unworkable or in need of significant retooling. While we endorse the notion that CAP should not "restrict the physician's flexibility when ordering drugs,"[21] state pharmacies laws do not permit a pharmacist to assign different prescription numbers to successive fills of a single prescription. Rather, prescription refills are always dispensed under the prescription number assigned to the original written order. A new prescription number is assigned only when a new written order is received. These practices are inconsistent with the prescription numbering system described in the preamble to the Proposed Rule. Indeed, CMS proposes allowing CAP vendors to split a physician's order of a beneficiary's entire course of treatment into appropriately spaced shipments but require the vendor to assign a separate prescription number to each shipment.[22]

Even though Social Security Act §1847B contemplates a patient-specific ordering process, CMS seems to believe that physicians should be able to devise ways of maintaining shipments of CAP drugs that are less burdensome that holding physically separate patient-specific inventories. CMS cautions that alternatives to physically separate patient-specific inventories must ensure program and product integrity and minimize the risks of diversion and medication errors, but the preamble to the Proposed Rule offers little specific guidance on what physicians will be expected to do beyond keeping "a separate electronic or paper inventory of each CAP drug obtained."[23] We are hard pressed to understand precisely what CMS has in mind, although we suppose it might be thinking about practices using automated drug dispensing and storage systems like those currently used by a few oncology practices to maintain and manage the inventories they handle under the buy-and-bill model.

State Medical Practice Acts do not, to our knowledge, impose restrictions on physicians' use of an automated dispensing system to control inventories of drugs that they purchase and administer under the buy-and-bill model.[24] The regulatory situation will change under CAP because, under that model, drugs must be dispensed by CAP vendors that are licensed under state Pharmacy Practice Acts. Given that reality, the approach of using automated dispensing and storage systems likely will face significant regulatory hurdles in many jurisdictions because of requirements built into state pharmacy laws to protect the integrity of products dispensed by pharmacies through automated systems. State pharmacy laws do not usually contemplate the placement of such machines in clinics or physician office settings. Rather, these laws tend to treat the machines as tools for use within pharmacies themselves or in institutions where pharmacists oversee pharmacy services.[25] Pharmacy

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responsible for . . . dispensing a prescription drug . . . compounding or labeling a drug or device, . . . [or] maintaining proper records for a drug or device." (Tex. Occ. Code Ann. § 551.003(33)).

21 70 *Fed. Reg.* 10753.

22 *Id.* at 10754.

23 *Id.* at 10756.

24 Cal. Bus. & Prof. Code §4170 prohibits a prescriber from using a dispensing device unless he or she personally owns the device and the contents of the device. This provision would seem to preclude the use of automated dispensing systems under CAP since the physician will not hold title to the drugs.

25 Florida law expressly permits the use of automated pharmacy systems in long-term care facilities, hospices, or state correctional institutions (Fla. Stat. Ann. § 465.0235) and in community pharmacies (Fla. Admin. Code Ann. §64B16-28.141). In both settings, the operation of the automated pharmacy system must be under the supervision of a Florida-licensed pharmacist. Illinois law permits all types of pharmacies except radiopharmacies to use automated dispensing and storage systems so long as a licensed pharmacist stocks the machines. (Ill. Admin. Code, tit. 68, § 1330.98(c)(7). Moreover, when injectable medications stored in their original multi-dose vials are dispensed through automated systems in Illinois, only a licensed pharmacist can return the multi-dose vial to the system for reuse (Ill. Admin. Code, tit. 68 § 1330.98(c)(10)). Texas permits both community and institutional pharmacies to use automated pharmacy systems to serve remote locations so long as the machines are under the continuous supervision of a pharmacist. (Tex. Occ. Code Ann. §562.109). By regulation, the Texas Board of Pharmacy has stipulated that remote automated systems may only be used to serve inmates in jails or inpatients in healthcare facilities licensed by the state. (Tex. Admin. Code, tit. 22 §291.20). California permits the use of automated drug delivery systems in certain government-operated and non-profit clinics (Cal. Bus. & Prof. Code §4186) as well as in licensed health care facilities (Cal. Bus. & Prof. Code §4186) so long as the systems are overseen by pharmacists, and in the case of clinic systems, stocked by a pharmacist. California also allows physician to use the machines in their practices, but only so long as they own both the machine and its contents.

laws in virtually every state will require CAP vendors to have a pharmacist oversee physician use of automated dispensing systems. CAP vendors will even be precluded from asking physicians or their staffs to place shipments of drugs into automated dispensing systems in some states because the pharmacy laws mandate that the machines be stocked or restocked by a licensed pharmacist.

CMS must do a better job in the final CAP rule of defining how it believes physicians can handle inventories of CAP drugs in their offices to avoid the burdens associated with storing each Medicare beneficiary's CAP drugs separately. If, despite the regulatory hurdles, automated pharmacy dispensing and storage systems are to be part of the solution, then CMS must address the expense of buying and maintaining the machines We doubt physicians would be willing to assume such costs as the price of participation in CAP. More importantly, we believe that the costs of acquiring and placing any automated dispensing systems needed to facilitate CAP must fall squarely on the CAP vendors since they are being contracted to dispense the drugs used under the new model of drug delivery and Social Security Act § 1847B(c)(6(B) expressly states they are to be paid for dispensing.

Given the legal limitations that CAP vendors will face if they try to use automated pharmacy systems to dispense drugs in physician offices and the prohibitions under most state pharmacy laws against retail pharmacies restocking unused drugs after they have been dispensed,[26] we are particularly troubled by CMS's proposal for dealing with CAP drugs that cannot be administered to the beneficiary for whom they were prescribed. In many states, it appears the proposed process could put the physician in the position of aiding and abetting the violation of state pharmacy laws – laws that were put in place to protect the product integrity of prescription drugs in the chain of commerce.

Generally speaking, where state legislatures have enacted laws that permit the restocking of previously dispensed drugs for resale, they have almost always done so in the context of unit-dose products that have been dispensed for inpatients of a healthcare facility (or inmates in correctional institutions) and have been returned to the same facility's pharmacy. There a pharmacist is required to inspect the drugs to ensure stability and integrity prior to restocking. None of the laws of which we are aware allow dispensed product to be redirected to another patient without going back to the dispensing pharmacy first.

The CAP proposal for redistributing unused dispensed products will primarily involve injectable and infusible products that may well require more sophisticated handling than pill-form drugs. Yet, the CMS proposal does not provide for any direct oversight of the redistribution by a trained pharmacist. Rather, the task of assessing the appropriateness of the restocking will fall to a nurse or a doctor who is much less qualified than a pharmacist to make informed judgment calls and to a pharmacist or pharmacist technician on the other end of the telephone who cannot see the condition of the product at issue. The strong financial incentive that a CAP vendor will have to authorize redistribution of unused drugs simply exacerbates the product integrity risks associated with the delinkage from direct pharmacist oversight that is inherent in the CAP model.

(Cal. Bus. & Prof. Code §4170). We have been unable to locate any such statutes or regulations in New York regulating the use of automated pharmacy systems.

[26] Under Fla. Stat. Ann. §465.016 pharmacies can be subject to disciplinary action if they restock unused drugs that have been dispensed to a patient unless the drug was a unit-dose packaged product dispensed in a hospital, nursing home, correctional facility or extended care facility. Fla. Admin. Code Ann. §64B-27-104 prohibits pharmacies from "placing in stock" any part of a prescription dispensed and returned, and Fla. Stat. Ann. §499.005(26) prohibits the removing of a dispensing label from a dispensed drug with the intent to further distribute the drug. Texas has a statute that expressly permits the restocking of drugs other than controlled substances dispensed to, but unused by, patients in healthcare facilities. (Tex. Stat. Ann. § 562.1085). By implication, restocking of dispensed products in other situations is not permitted. Ill. Admin. Code, tit.68 §1330.95(f) prohibits pharmacists and pharmacies from "accepting from patients or their agents for reuse, reissue or resale any dispensed medications." New York limits the restocking of dispensed drugs to unit-dose products in the institutional setting. (NYS Professions, Regents Rules, Part 29, Unprofessional Conduct, §29.7).

Redirecting unused drugs dispensed by a CAP vendor from the intended recipient to another patient could expose physician practices to tort liability if errors in judgment are made about the quality or stability of the drug or if a medication error results because of the practice's handling of the redirected product. Physicians wishing to take advantage of the drug replacement provisions under CAP will need to develop and implement new systems to mitigate the risk of medication errors and to document the vendor's input about the suitability of a particular dose of drug for the proposed redirection. Prudent physicians likely will demand indemnification from CAP vendors when reuse decisions about drugs belonging to the vendor, not the physician, are made based on discussions with the CAP pharmacist. We urge CMS to build requirements for appropriate indemnities into the final rule.

Quality, Service, Financial Performance and Solvency Standards

Issue Identifier: Contracting Process – Quality and Product Integrity Aspects

In an effort to ensure the stability of CAP, MMA directs CMS to require CAP vendors to meet standards for quality, service, financial performance and solvency that include appropriate procedures for the resolution of physician complaints and grievances. Unfortunately, the statute offers few specifics regarding these standards, and the proposed rule does not define all of the standards to which the vendors will be held. As it has done in the DMEPOS Supplier manuals, CMS should issue CAP guidance that defines measurable quality, service, financial performance and solvency standards.

With respect to Quality and Service Standards, we believe CMS should focus on standards related to shipment errors (e.g., wrong drug or dose; wrong quantity; damaged packaging; inadequate refrigeration; counterfeit product, etc.) and timely deliveries, both for routine and emergency deliveries. We also believe that the required physician call centers need to operate a minimum of 12 hours per day and that call management standards should tightly limit ring time, hold time, and dropped calls.

When it comes to Clinical Standards, we applaud CMS's decision to make the local carriers the arbiters of coverage and medical necessity decisions. Oncology drugs can be extremely expensive, compendium-supported off-label usage is statutorily mandated, and off-label usage supported by peer-reviewed literature is commonly reimbursed. As a result, CMS is right not to place decisions about coverage and medical necessity in the hands of vendors.

We are concerned, however, about the administrative burden on physician practices that will result from the CAP Election Agreement's requirement that physicians appeal all denied drug administration claims. The proposed rule provides no guidance on how many levels of appeal the physician must pursue, but the draft Election Agreement requires appeal through the reconsideration level. For clarity, we urge CMS to include this limitation in the final rule. The burden of appealing every denied drug administration claim is heightened by the pending changes in the claims appeal process that become effective on May 1, 2005. Given the magnitude of those changes, CMS should require the CAP vendor to request clinical literature from drug manufacturers needed to support appeals of drug administration denials.

We are also concerned that the proposed rule ignores the significant risk that physicians could face litigation over adverse drug events due to drugs provided by a CAP vendor. We strongly urge CMS to require CAP vendors to indemnify physicians for all costs, including reasonable attorney's fees, associated with the defense of all such actions where the physician is ultimately exonerated. The indemnification may be prorated if the physician is found to be partly liable and there is a rational basis for apportioning costs between the CAP vendor and the physician.

With respect to Financial and Solvency Standards, we commend CMS's decision to assess CAP bidders using Federal Acquisition Regulation (FAR) criteria, adopt FAR business integrity and conflicts of interest standards, and review third-party information on the structure and effectiveness of CAP bidders' internal control systems. The proposed rule does not specify how CMS will ensure ongoing compliance with vendor performance requirements, however, so CMS should issue a detailed guidance document, require CAP vendors to report key performance statistics quarterly, and consider imposing contractually defined financial penalties for sub-par performance in addition to the imposition of False Claims Act liability that vendors face.

CAP Vendor Credentials

Issue Identifier: Bidding Entity Qualifications

CMS is justifiably concerned about the need to ensure that CAP vendors are qualified to provide the services called for under Social Security Act §1847B. We disagree, however, with two of the approaches that CMS has proposed for qualifying potential candidates.

CAP vendors must be licensed as a pharmacy in each state in their assigned service area. Although they may need to be licensed as a wholesaler as well, that credential alone is not sufficient because wholesalers are not permitted to ship patient-specific drug orders dispensed pursuant to a prescription. By focusing so extensively on distribution experience and the wholesaler credential, CMS is emphasizing the commodity aspect of the services that CAP vendors must provide, not the high-value aspects of those services.

Instead, CMS should focus on the dispensing aspects of a CAP vendor's duties and pharmacy credentials. Just as important, CMS should place great emphasis on vendors' competence in patient-centric drug management services, in billing, claims processing, coordination of benefits and collections, and in their responsiveness to local market needs. Licensed pharmacies are more likely to have experience dealing with patient and physician complaints and are more likely to have, and be used to operating under, a code of conduct and a robust compliance program like that envisioned under 42 CFR §414.914(c). These credentials seem much more relevant than CMS's current focus on distribution capabilities.

We also disagree with the proposal to require all acceptable applicants to have 3 years of experience in "the business of furnishing Part B injectable drugs." Years of experience as a distributor are a poor proxy for the skill sets and capacity measures that will characterize efficient and effective CAP vendors. Moreover, the 3-year requirement will restrict competition and prevent new and higher quality entities from entering the market. A better approach would be to require that a bidder hold current pharmacy and wholesaler licenses in each state in the service area for which it is bidding and be enrolled as a Medicare supplier. CMS should then evaluate each applicant's financial performance and solvency against pre-established criteria to identify organizations that are sufficiently capitalized to take on the challenge.

Similarly, CMS should collect information on personnel statistics, warehouse and dispensing capacities, distribution center locations, inventory sourcing relationships and the like and compare that information to pre-established criteria designed to ensure that the applicant has the wherewithal to handle the dispensing load CAP vendors can expected to face. It will be particularly important for vendors to have a broad geographic presence, either directly or through subcontract arrangements, with a wide network of pharmacies. Otherwise the vendor will be unable to make routine and emergency deliveries in time frames that meet patient needs.

CMS also should gather data about each applicant's experience in critical functions such as pharmacy services management, billing and collection, and compliance to evaluate the applicant's ability to provide the level of service and quality necessary to support physicians who furnish Part B drugs in their offices and the Medicare beneficiaries who depend on them for care. As part of this process, CMS should consider checking references to assess how satisfied customers of a size commensurate with that of most oncology practices have been with past service.

In each of these areas, the bidder's qualifications can be assessed not merely on the basis of their experience in the commodity service of distribution but in crucial service functions that will determine the difference between vendors who can safely and reliably serve CAP physicians needs, and those that cannot.

Shipping Standards

Issue Identifier: Bidding Entity Qualifications

Under Social Security Act §1847B(b)(2)(A)(i)(II), CAP vendors are required to have arrangements in place sufficient to permit shipment "at least 5 days each week for competitively biddable drugs and biologicals . . . and for the timely delivery (including for emergency situations) of such drugs and biologicals in the area under the contract." (See also 42 CFR 141.914(f)(2)). We appreciate CMS's request for comments both on "how to define timely delivery for routine and emergency drug shipments" and on the "feasibility of providing same day deliveries for orders received for emergency situations" (70 *Fed. Reg.* 10745,10760 (March 4, 2005)).

We believe that the proposed timelines for routine and emergency delivery are inadequate and that vendors must be required to make routine deliveries anywhere in their service area within 24-hours of a practice's submission of a new prescription 7 days a week. We base this recommendation on three principle considerations. First, it is not unusual for oncology practices to operate 6 and 7 days a week to meet their patients' needs. Second, it is estimated that approximately one-third of treatment plans must be modified on the day of treatment due to changes in a patient's health status. Third, the unavailability of drugs needed on the day of treatment would pose a significant burden on patients who would have to return another day for treatment. This burden can be particularly severe in rural areas were patients may have to travel long distances to receive cancer care.

CMS has the authority to require that CAP vendors be able to delivery drugs within 24 hours 7 days a week under the statutory language in Social Security Act §1847B(b)(2)(A)(i)(II). That provision imposes two standards on CAP vendors: the ability to make timely deliveries and the ability to ship *at least* 5 days each week. We believe that CMS should use its authority to define "timely delivery" as a 24-hour turn around and 7-day-a-week delivery services. We fear that anything less could jeopardize the ability of cancer care specialists to meet their patients' clinical needs.

We believe CMS should not rely on an expectation that oncologists who choose CAP will continue to maintain an adequate inventory of drugs that can be used to treat Medicare patients in emergencies under the inventory replacement provisions of the CAP rule. CAP is expected to spur growth in commercial payers' mandatory vendor imposition (MVI) programs. As a result, some physicians who elect CAP and continue offering in-office drug administration services may cease to maintain any on-site drug inventories. Even those practices that maintain inventories may limit them for a variety of reasons, including differences in the clinical needs of their Medicare and non-Medicare patient bases.

Finally, we note that neither the changes to 42 CFR 414.902 set forth in the proposed rule nor the text of the existing regulation define the term "emergency." It is essential for the definition of emergency to be clearly set forth in the final rule and not left to the discretion of each CAP vendor or to the discretion of local carriers tasked with adjudicating practices' claims for drug administration services. Moreover, the definition should turn on the treating physician's clinical judgment that patient health would suffer from delay in treatment, not on the CAP vendor's or the local carrier's remote assessment of the situation.

We therefore urge CMS to implement the "timely delivery" requirement established by MMA as requiring CAP vendors to be able to deliver ordered drugs within 24 hours, 7 days a week.

The ASP +6% Limitation on Acceptable CAP Bids Is Inappropriate

Issue Identifier: CAP Bidding Process – Evaluation and Selection

We understand that CMS intends to contract only with qualified CAP bidders that submit composite bids with a weighted average price per HCPCS unit that is no greater than 106% of the weighted ASP for the drugs in the category. US Oncology has consistently taken the position that reimbursement at 106% of ASP is inadequate to cover physicians' costs for chemotherapy drugs and for pharmacy management services and other associated expenses, including bad debt, that are currently not considered in the practice expense component of the drug administration G codes.

Just as we believe this level of reimbursement is inadequate for physicians under the buy-and-bill model, so too do we view reimbursement at 106% of ASP to be inadequate under the CAP model. Competition will not cause manufacturers of most single-source drugs to discount their products to CAP vendors or to any other class of buyer that must be considered when Best Price is calculated. And, like physician practices nationwide, bad debt will pose a major financial challenge to CAP vendors.

In addition, CAP vendors will incur significant middleman costs, including administrative, dispensing, shipping, product disposal, and bad debt costs. These costs are borne by physicians practices everyday, but CAP vendors will likely face even greater difficulty collecting due to the time delay between the dates of treatment and payment, as well as their lack of a direct relationship with patients. Beneficiaries who are already contending with deductibles and coinsurance payments not covered by secondary insurance, travel expenses, custodial care expenses, costs associated with changed dietary needs, etc., may place a relatively low priority on paying their CAP vendors.

Just as the absence of personal relationships between beneficiaries and CAP vendors is likely to exacerbate the vendors' bad debt collection problems, we fear it will also exacerbate some vendors' use of overly aggressive collection efforts, including decisions to stop providing drugs for patients who are too far in arrears. The Practicing Physicians Advisory Council has also raised this concern and proposed that CMS address it in the final CAP rule by mandating that vendors advance credit to patients unable to afford their coinsurance payments. CMS should go a step further and ask that the vendors also be required to have in place procedures for assessing indigence and waiving coinsurance when a non-Medicaid-eligible beneficiary's income, assets, and medical expenses meet certain pre-established criteria. Ideally, these procedures should incorporate the assistance of social workers trained to explore all payment options and assistance programs available to the individual.

Unlike the situation with physicians where reimbursement for Part B drugs supplied under the buy-and-bill model is set by statute at 106% of ASP, CMS may have the discretionary authority under Social Security Act §1847B to permit payments to CAP vendors at any level necessary to compensate them fairly and appropriately for their services. It appears that Congress only expected competition under the CAP model to save money on multi-source drug products, not single-source drugs and biologicals.

Pre-defining an unrealistically low reimbursement cap could under-capitalize vendors, resulting in too few qualified bidders, the provision of improper services, and patient harm. Therefore, CMS should either abandon the notion that CAP will save money in the aggregate for Medicare Part B or phase in the program slowly by starting with a small group of drugs or with a specialty that does not use "incident to" drugs intensively to test the impact of an potentially under-reimbursed CAP model on beneficiary access to care and on the robustness and financial viability of the CAP vendor market.

In either case, one conclusion should be recognized: just as 106% of ASP is too low in the buy-and-bill model, so too is it unsustainable in CAP.

CAP Drug Categories

Issue Identifier: Categories of Drugs To Be Included Under the CAP

The design and implementation of a competitive acquisition program for Part B drugs is an enormous undertaking. It is also an undertaking that will move Medicare into largely uncharted waters. That fact alone argues for a cautious approach.

Although CMS has managed two competitive acquisition demonstration projects[27] for certain types of durable medical equipment, prosthetics and supplies ("DMEPOS")[28] in limited geographic markets, it has never organized and run a competitive acquisition program on a national or even a regional scale. The Part B drug CAP differs significantly from the DMEPOS demonstrations because of the complicated state licensing and regulatory schemes with which interested vendors will be faced, the criticality of most of the products involved from a beneficiary perspective, and, in many instances, the single-source nature of the drugs to be furnished. In addition, DMEPOS is sold directly to Medicare beneficiaries who use the products in their homes. Because Part B drugs are not self-administrable, vendors will be required to work with physicians who, acting as an agent for the beneficiary, will receive the drugs the CAP vendors dispense and bill and who then will be reimbursed by Medicare only for administrating those drugs. The triangulated nature of the new drug delivery system under CAP will necessitate major changes in the Medicare claims processing systems that will go beyond anything required to implement the DMEPOS demonstrations.

With DME, there were numerous established suppliers, operating in a largely unregulated environment from the state licensure perspective, in each demonstration area anxious to compete for a bigger share of the Medicare market for particular categories of equipment. Because participation in the demonstration by Medicare beneficiaries living in the test areas was mandatory, the bidders knew the size of the potential market. The bidders also ran established businesses and clearly understood the cost structures of those businesses.

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[27] One demonstration was conducted in Polk County, Florida, which has a population of about 500,000 people. That project ran for approximately three years. The second demonstration lasted approximately two years and covered the San Antonio, Texas MSA, which has a population of about 1,600,000.

[28] The demonstration in Polk County involved enteral nutrients, equipment, and supplies; hospital beds and accessories; oxygen contents, equipment and supplies; surgical dressings; and urological supplies. The San Antonio demonstration involved hospital beds and accessories; nebulizer inhalation drugs; manual wheelchairs and accessories; noncustomized general orthotics; and oxygen contents, equipment, and supplies.

Unlike the situation with single-source drugs that are the standard of care for many cancer patients today, each product category subject to DMEPOS competitive bidding included numerous items under most HCPCS codes subject to the demonstration. Again, unlike the situation that will face manufacturers of Part B drugs in 2006, the discounts extended to DMEPOS competitive bidders did not impact Medicare reimbursement for the manufacturer's product in locations outside the demonstration area. In other words, with DMEPOS, CMS could count on an adequate supply of qualified bidders positioned to put forth bids consistent with required quality and service standards without sacrificing reasonable profitability and jeopardizing solvency. Furthermore, the product categories included in the DMEPOS demonstrations are not generally seen as carrying the same level concern about product integrity or medical errors as do Part B drugs. Therefore, if, despite CMS's best efforts, the DMEPOS CAP vendors stinted on quality or service in the name of profit, the likely outcomes for beneficiaries were not as potentially significant as they could be if problems develop with the Part B drug CAP.

The GAO issued a final report to Congress assessing the DMEPOS demonstrations in September 2004.[29] In that report, the GAO made recommendations to assist CMS with the national roll-out of competitive bidding for DMEPOS mandated by MMA §302 beginning with 10 MSAs in 2007 and extending to 80 MSA in 2009. Significantly, those recommendations included a suggestion that CMS consider conducting more competitive bidding demonstrations for items and services not in the original demonstrations prior to the beginning of the MMA-mandated implementation of CAP for DMEPOS. GAO also espoused the development of: (1) standardized approaches for the bid solicitation, (2) procedures for monitoring beneficiary satisfaction, and (3) procedures for soliciting input from individuals with technical knowledge about the DMEPOS being provided to beneficiaries by the vendors. We presume from these recommendations that the procedures used during the demonstrations were not deemed adequate for a national roll-out of the program.

To us, these types of recommendations, particular the one about the need to conduct further demonstration projects after a three year run for the Polk County project and a two year run for the San Antonio project, argue strongly for taking a slow approach to the implementation of the Part B drug CAP. So to do the constraints that the short timelines and the manpower squeeze under MMA have placed on the agency's normal deliberative processes. We would hope that CMS would agree given the lessons learned from the DMEPOS demonstration projects. In its final report on the projects,[30] CMS characterized the demonstrations as successful but acknowledged not all went smoothly. It then observed "one of the benefits of conducting demonstrations projects is the ability to learn from the demonstration and apply the lessons if the demonstration is adopted on a wider scale."[31]

US Oncology therefore does not endorse diving into a national competitive acquisition program involving all Part B drugs used in "incident to" services. We would prefer to see CMS start by getting its feet wet first with an approach that involves a regional or national test involving a limited set of drugs that are typically administered by a physician specialty that uses drugs less intensely than oncology. Taking this tact would allow CMS to resolve any inadequacies in its application and vendor selection procedures and its quality and service requirements, correct glitches in CAP upgrades to its claims processing systems, work out handling issues stemming from state regulations, assess and adjust for changes in practice expenses attributable to CAP, and complete the work needed to better match the reimbursement rates for drug administration services to actual costs for the various specialties before promotes CAP as a viable option more universally.

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[29] "Medicare: Past Experience Can Guide Future Competitive Bidding for Medical Equipment and Supplies," GAO-04-765 (Sept. 2004) (http://www.gao.gov/new.items/d04765.pdf)

[30] "Evaluation of Medicare's Competitive Bidding Demonstration for DMEPOS: Final Report," A. Meadow *et al.*, RTIP Project 07346.002.011 (Nov. 2003) (http://www.cms.hhs.gov/researchers/reports/2004/karon.pdf)

[31] *Id.* at p 10.

Adjusting the roll-out schedule for CAP to avail itself of the type of learning that typically comes from demonstration projects would also serve as an insurance policy against the possibility that too few vendors will apply for the Part B drug CAP to make the program viable. We note that CMS observed that the categories of DMEPOS most appropriate for CAP were those where cost were high (which is certainly the case with many Part B drugs) and where there were a sufficient number of bidders to allow competition to drive down prices.[32] Otherwise the cost of operating the program and maintaining quality and service will outweigh the savings. We understand that 15 organizations expressed interest in CAP when CMS published a Request for Information in December 2004,[33] but we note that document did not stipulate that acceptable bids would have to be at or below a weighted average HCPCS price equal to 106% of the weighted ASP for the drugs in the category. We therefore wonder whether the number of interested applicants will be as high under this restriction on costs.

As these comments illustrate, numerous issues complicate the safe, effective, and efficient implementation and operation of the Competitive Acquisition Program. As CMS works through these issues, there may be a temptation to do so on a regional rather than a national basis. We would therefore like to conclude these comments by addressing the question whether vendors should be required to submit and operate under national or regional contracts. Although implementation of CAP for oncology should not occur until issues including those submitted here are addressed, when CMS is ready to implement an oncology CAP it must do so on the basis of national vendor contracts only.

In our mobile society, patients are no more apt to remain in a single location without exception than any other American. With many so-called "snowbird" seniors also making regular transit between northern and southern states, the reality is that many cancer patients must be able to access care in multiple states. If CAP vendors are permitted to operate on a regional basis, a substantial risk of confusion (on the part of patients and physicians alike) and treatment disruption will face many of the nation's mobile seniors. To prevent such an outcome, CAP vendors must be able and required to serve patients on a national scale.

* * * * *

Thank you for this opportunity to provide these comments on behalf of US Oncology. We are grateful for the opportunity to engage in substantive discussions and practice site visits with CMS officials. We therefore stand ready should you have any questions about the issues, concerns, suggestions and data analyses discussed above or would like to discuss these comments further.

Sincerely,

Leo E. Sands
Chief Administrative Officer
and Executive Vice President

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[32] "Evaluation of Medicare's Competitive Demonstration for DMEPOS: First Year Annual Evaluation Report" A.Meadow, RPTI 7345-002-008 (Jan. 2001) (http://www.cms.hhs.gov/researchers/reports/2004/rtc_DMEPOS.pdf).

[33] "Competitive Acquisition Program (CAP) Part B Drug and Geographical Area of Coverage: Request for Industry Comments" (Dec. 17, 2004) http://www.cms.hhs.gov/contracts/caprfi.asp.

Drug and Drug Administration
CMS Utilization
Five Physician Practice
2005 and 2006
Cost and Reimbursement Analysis

2005 Medicare Reimbursement with Demonstration Project

	Drugs	Drug Administration	Demonstration Project	Total w/o E&Ms	E&M	Total w/ E&M
Cost	$ 2,160,936	$ 796,549	$ -	$ 2,957,485	$ 465,582	$ 3,423,067
Reimbursement	$ 2,290,593	$ 476,924	$ 167,984	$ 2,935,500	$ 564,039	$ 3,499,539
Difference	$ 129,656	$ (319,625)	$ 167,984	$ (21,985)	$ 98,457	$ 76,472
	6.0%	-40.1%		99%	21.1%	2.23%

Medicare Payment (80% of Total Reimbursement)

	Drugs	Drug Administration	Demonstration Project	Total w/o E&Ms	E&M	Total w/ E&M
Reimbursement	$ 1,832,474	$ 381,539	$ 134,387	$ 2,348,400	$ 451,231	$ 2,799,632

Patient Payment (20% of Total Reimbursement)

	Drugs	Drug Administration	Demonstration Project	Total w/o E&Ms	E&M	Total w/ E&M
Reimbursement	$ 458,119	$ 95,385	$ 33,597	$ 587,100	$ 112,808	$ 699,908

Average Co-Payment Collection (50% of Patient Payment)

	Drugs	Drug Administration	Demonstration Project	Total w/o E&Ms	E&M	Total w/ E&M
Reimbursement	$ 229,059	$ 47,692	$ 16,798	$ 293,550	$ 56,404	$ 349,954

Total Reimbursement with Average Co-Payment Collections

	Drugs	Drug Administration	Demonstration Project	Total w/o E&Ms	E&M	Total w/ E&M
Cost	$ 2,160,936	$ 796,549	$ -	$ 2,957,485	$ 465,582	$ 3,423,067
Reimbursement	$ 2,061,533	$ 429,231	$ 151,186	$ 2,641,950	$ 507,635	$ 3,149,586
Difference	$ (99,403)	$ (367,318)	$ 151,186	$ (315,535)	$ 42,054	$ (273,482)
	-4.6%	-46.1%		89%	9.0%	-7.99%

2006 Medicare Reimbursement with the Competitive Acquisition Program (CAP)

	Drugs	Drug Administration	Demonstration Project	Total w/o E&Ms	E&M	Total w/ E&M
Cost	$ -	$ 796,549	$ -	$ 796,549	$ 465,582	$ 1,262,131
Reimbursement	$ -	$ 443,345	$ -	$ 443,345	$ 539,786	$ 983,130
Difference	$ -	$ (353,204)	$ -	$ (353,204)	$ 74,204	$ (279,000)
		-44.3%		56%	15.9%	-22.1%

Medicare Payment (80% of Total Reimbursement)

	Drugs	Drug Administration	Demonstration Project	Total w/o E&Ms	E&M	Total w/ E&M
Reimbursement	$ -	$ 354,676	$ -	$ 354,676	$ 431,828	$ 786,504

Patient Payment (20% of Total Reimbursement)

	Drugs	Drug Administration	Demonstration Project	Total w/o E&Ms	E&M	Total w/ E&M
Reimbursement	$ -	$ 88,669	$ -	$ 88,669	$ 107,957	$ 196,626

Average Co-Payment Collection (50% of Patient Payment)

	Drugs	Drug Administration	Demonstration Project	Total w/o E&Ms	E&M	Total w/ E&M
Reimbursement	$ -	$ 44,334	$ -	$ 44,334	$ 53,979	$ 98,313

Total Reimbursement with Average Co-Payment Collections

	Drugs	Drug Administration	Demonstration Project	Total w/o E&Ms	E&M	Total w/ E&M
Cost	$ -	$ 796,549	$ -	$ 796,549	$ 465,582	$ 1,262,131
Reimbursement	$ -	$ 399,010	$ -	$ 399,010	$ 485,807	$ 884,817
Difference	$ -	$ (397,539)	$ -	$ (397,539)	$ 20,225	$ (377,313)
		-49.9%		50%	4.3%	-29.89%

Assumptions:
Overall:

1/ Utilization based on the 2005 utilization reflects claims received through June 30, 2004 and is estimated to be 98 percent complete. The data reflects an adjustment to estimate a complete year's utilization. Specialty Utilization File Used To Create Resource-Based Practice Expense Relative Value Units For Calendar Year 2005 (Final Rule 11/2004) for Oncology Specialties Only: Hematology (82), Hematology/Oncology (83) and Medical Oncology (90)

2/ 2005 utilization is reprised based on 2005 with the 3% "Transitional Fee" and 2006 with 0% "Transitional Fee as Medicare expected reimbursement.

3/ Estimated Five Physician Practice is based on CMS Physician Directory Updated in December 00, 2004 for the three Oncology Specialties Only: Hematology (82), Hematology/Oncology (83) and Medical Oncology (90): http://www.medicare.gov/PhysicianSearch.asp. Medicare Physician count for the these specialties are 9,762. Based on "Centers for Disease Control and Prevention ("CDC") data currently indicate that more than **80 percent** of all chemotherapy treatment encounters occur in non-hospital outpatient settings (freestanding oncology physician's offices and community cancer centers)." ONS 3/01 **Reimbursement vs. Reality A Discussion Paper on Medicare Payments for Cancer Treatment. The estimated total Medicare Physicians in a free**

4/ To estimate 2006 drug administration reimbursement shortfalls per physician per patient annually the following figures were used in the calculation.

Cost	$ 159,309 78	300 Number of Patients per physician per year
Reimbursement	$ 79,802 05	170 Number of Cancer Patients per physician per year
Difference	$ (79,508)	44% Medicare %
Per Beneficiary	$ (1,060 10)	75 Medicare Cancer Patients per physician per year

5/ "Accepting assignment means that Physicians accept the payment rates in the physician fee schedule as payment in full with no further billing of beneficiaries for amounts above those rates. Under assignment, the physician receives the program payment, which is 80 percent of the total payment amount, directly from Medicare. The beneficiary is responsible for the other 20 percent. Without assignment, the beneficiary receives the program payment, and the physician bills the beneficiary for the total." The Report to the Congress: Medicare Payment Policy , March 2003 Section 2B: Assessing payment adequacy and updating payment for a physician services pg. 72

6/ The 50% average Co-Payment collection is based on OS Oncology reimbursement experience.

Drug Reimbursement and Cost:

7/ MCR 2005 and 2006: ASP based on First Quarter 2005 Payment Limits updated through February 3, 2005 published by CMS at www.cms.gov

8/ Drug cost is Average Sales Price based on First Quarter 2005 Medicare Payment Limits updated through February 3, 2005

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9/ 2005 Drug Administration Codes based on published change by CMS in the Federal Register Vol. 69, No. 219 Monday, November 15, 2004

10/ 2006 and 2006 Conversion Factor: Based on reimbursement published by CMS, 2004 MPDIMA

The Conversion Factor for 2005 is $37.8075 based on Section 1848(d)(4)(F) requirement by MMA that the update for 2005 shall be not less than 1.5 percent.

In this Analysis, the Conversion Factor for 2006 is based on an estimated 4.4% decrease from $37.8974(2005 Conversion Factor). In a letter dated March 31, 2005 to the Medicare Payment Advisory Commission, CMS also said that physicians' Medicare reimbursement will be cut 4.1 percent in 2006 as a result of the spending increases and how they are calculated via the sustainable growth rate formula (SGR) incorporated into Medicare's physician fee schedule

11/ Drug Administration cost is based on The Moran Company | Practice Expense Reimbursement for Cancer Care Services: Methodology Evaluation & Assessment of Alternative Policies. Final Report September 23, 2004. Practice Expense for Oncology Specialties Hematology (82), Hematology/Oncology (83) and Medical Oncology (90) is 48% more than the Practice Expense Medicare Reimbursment due to "Scaling" and "Blending." Table 2-3,1,4.

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2006 Medicare Reimbursement with the Competitive Acquisition Program (CAP)

	Drugs	Drug Administration	Demonstration Project	Total w/o E&Ms	E&M	Total w/ E&M
Cost	$ -	$ 796,549	$ -	$ 796,549	$ 465,582	$ 1,262,131
Reimbursement	$ -	$ 467,898	$ 167,984	$ 635,882	$ 569,680	$ 1,205,561
Difference	$ -	$ (328,651)	$ 167,984	$ (160,667)	$ 104,098	$ (56,569)
		-41.3%		80%	22.4%	-4.5%
		59%				

Medicare Payment (80% of Total Reimbursement)

	Drugs	Drug Administration	Demonstration Project	Total w/o E&Ms	E&M	Total w/ E&M
Reimbursement	$ -	$ 374,318	$ 134,387	$ 508,705	$ 455,744	$ 964,449

Patient Payment (20% of Total Reimbursement)

	Drugs	Drug Administration	Demonstration Project	Total w/o E&Ms	E&M	Total w/ E&M
Reimbursement	$ -	$ 93,580	$ 33,597	$ 127,176	$ 113,936	$ 241,112

Average Co-Payment Collection (50% of Patient Payment)

	Drugs	Drug Administration	Demonstration Project	Total w/o E&Ms	E&M	Total w/ E&M
Reimbursement	$ -	$ 46,790	$ 16,798	$ 63,588	$ 56,968	$ 120,556

Total Reimbursement with Average Co-Payment Collections

	Drugs	Drug Administration	Demonstration Project	Total w/o E&Ms	E&M	Total w/ E&M
Cost	$ -	$ 796,549	$ -	$ 796,549	$ 465,582	$ 1,262,131
Reimbursement	$ -	$ 421,108	$ 151,186	$ 572,294	$ 512,712	$ 1,085,005
Difference	$ -	$ (375,441)	$ 151,186	$ (224,255)	$ 47,130	$ (177,125)
		-47.1%		72%	10.1%	-14.03%

Assumptions:
Overall:

1/ Utilization based on the 2003 utilization reflects claims received through June 30, 2004 and is estimated to be 98 percent complete. The data reflects an adjustment to estimate a complete year's utilization. Specialty Utilization File Used To Create Resource-Based Practice Expense
Relative Value Units For Calendar Year 2005 (Final Rule 11/2004) for Oncology Specialties Only: Hematology (82), Hematology/Oncology (83) and Medical Oncology (90)

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Difference	$	(44,851)	44% Medicare %
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The Conversion Factor for 2005 is $37.8075 based on Section 1848(d)(4)(F) requirement by MMA that the update for 2006 shall be not less than 1.5 percent.

In this Analysis, the Conversion Factor for 2006 is based on an estimated 3% increase from $37.8074(2005 Conversion Factor) to $38.27.65 (2006 Conversion Factor). This analysis extends the Chem-therapy Demonstration Project to 2006.

11/ Drug Administration cost is based on The Moran Company | Practice Expense Reimbursement for Cancer Care Services: Methodology Evaluation & Assessment of Alternative Policies. Final Report September 23, 2004. Practice Expense for Oncology Specialties Hematology (82), Hematology/Oncology (83) and Medical Oncology (90) is 48% more than the Practice Expense Medicare Reimbursment due to "Scaling" and "Blending" Table 2.0.14.

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APR 1 2 [illegible]

Erin Hoffman
St. Luke's House
6040 Southport Drive
Bethesda, MD 20814

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1325-P
PO Box 8010
Baltimore, Maryland 21244-8010

April 8, 2005

Dear Sir or Madam,

I am writing to you regarding Medicare Part B: Competitive Acquisition of Outpatient Drugs and Biologicals. I strongly urge you to include all of the mental health therapeutic categories and psychiatric drugs in the proposed Competitive Acquisition Program, Phase I, scheduled to be effective January 1, 2006. Please ensure that the rule also prevents discontinuation of therapy the vendors selected. Such measures will improve consumer access to care by simplifying the reimbursement process.

Outpatient Mental Health Clinics that serve those consumers who struggle with serious and persistent mental illnesses, such as schizophrenia, have found that often the most clinically effective symptom-management strategy are long-acting, non self-administered, injectable medications (e.g. Risperdal Consta). Currently the Buy and Bill process is the only option that approximately 50% of consumers, those under Medicare Part B, have for obtaining such drugs. This option is very expensive, administratively burdensome, and financially risky for both non-profit providers and needy consumers alike.

I strongly urge you to include all of the mental health therapeutic categories and psychiatric drugs in the proposed Competitive Acquisition Program, Phase I, scheduled to be effective January 1, 2006 and ensure that the rule also prevents discontinuation of therapy the vendors selected.

Thank you for your consideration of this most serious matter.

Sincerely,

Erin R Hoffman

Erin R. Hoffman
St. Luke's House
Residential Counselor

1105

NAMI – Greater Dayton
817 Cushing Avenue
Kettering, OH 45429

MAY - 2 2005

April 25, 2005

RE : CMS -1325-P: Medicare Part B – Competitive Acquisition of Outpatient Drugs and Biologics

NAMI Greater Dayton applauds Medicare's' covering of psychiatric injectables! Approximately 40% of consumers with schizophrenia are eligible for Medicare coverage. We stand firm in our belief that injectable therapy is a great treatment option for consumers suffering from schizophrenia as non-compliance to oral medications and their side-effects is so common with that diagnosis.

However, we do have major concerns regarding the "Buy and Bill' coverage for Medicare. We are currently experiencing problems in Montgomery County with Medicaid coverage with the injectables, even though; the injectables are 100% Medicaid reimbursable! The Community Mental Health Centers are extremely reluctant to administer injectables as the out-of-pocket expense is great until reimbursement is received. "Buy and Bill" would only delay the reimbursement further at it reimburses at less than cost and requires a second player; Medicaid or 'out of pocket'.

The reimbursement procedure would definitely be a barrier to consumers easily accessing injectables. Many of our consumers are currently receiving their injectables through hospital emergency rooms due to the current Medicaid reimbursement procedures.

The need for injectable therapy is great but if the access to injectables is inhibited by reimbursement procedures, many consumers will either be denied access to injectables or will not be able to receive the injectables at their Community Mental Health Center. The current reimbursement procedures will have a great impact on the process. CAP would improve consumer access to care and NAMI -- Greater Dayton appeals to you to streamline procedures to a competitive acquisition program. CAP will improve consumers' access to care as it would allow injectables to be handled as a pill, eliminating the coverage and process issues (no need to buy and bill, no financial risk to the provider).

Injectables are hope for the future! We cannot let billing procedures interfere with the treatment!

Thank you,

NAMI-Greater Dayton

Linda Troutman
Kathy Kuritar

Jim Greene

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APR 12 2005

My name is Linda Severance. I am a Social Service Worker with Valley Mental Health in Salt Lake City, Utah. Our unit specifically works with the homeless mentally ill population. Medicaid and Medicare are the only insurance these people have a chance of obtaining to care for all their medical needs.

It concerns me that VMH may need to purchase and subsequently bill in order to obtain medications for clients. More specifically:

-you're asking VMH to assume financial responsibility and the risk. Working with people that don't necessarily have a funding source to pay for anything makes us always strapped financially in our efforts to provide for them. So we're also assuming a credit risk;

-then we will be asked to come up with an infrastructure that does not currently exist which would deal with billing, inventory and client tracking;

-but the biggest concern is providing optimal care in the midst of worrying about all the funding concerns. Which will ultimately be the priority? Giving clients a medication for lack of choice versus giving a client the med the provider deems necessary for appropriate treatment?

Thank you for your time,

Linda Severance

April 4, 2005

I am writing to express concerns about the proposed changes that would affect access to care pertaining to our clients that we serve in our Community Mental Health Center. Valley Mental Health serves the chronically mentally ill and due to the high numbers of people we serve who carry a diagnosis of Schizophrenia and Bipolar Disorder I would like to see the proposed changes that would medications such as Haldol, Prolixin and Risperdal Consta which are the only means we have of treating and improving adherence to medications.

Due to shrinking funding of federal and state programs we do not have the resources it would take to provide the increased processes related to billing for these medications.

We have an ethical directive to serve our clients using the best medications possible, and using less than appropriate medications does not serve this ethical responsibility.

Thanks you for your time,

APRN

Mitzy Stewart APRN

April 23, 2005

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Part 414

[CMS-1325-P]

Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals under Part B

Dear Secretary:

PBI appreciates the opportunity to comment on the Competitive Acquisition of Outpatient Drugs and Biologicals under Part B provision within the Medicare Prescription Drug, Improvement and Modernization Act of 2003; specifically file code CMS-1325-P. PBI is a group purchasing organization for pharmacies and physicians servicing the alternate care market; i.e., non-acute (not hospital based) and non-retail. Our members include home infusion pharmacies, long term care pharmacies, home medical equipment providers and oncology clinics.

As a group purchasing organization, PBI is actively involved with 300 plus pharmaceutical and supply manufacturers, drug wholesalers and specialty distributors. We manage over 400 contracts and are very familiar with pricing, pharmacy and distribution systems that will be affected by this proposed rule.

While we understand the need, and fully support, the Secretary's desire to reduce Part B drug costs for physician practices, we have many concerns about the operational and financial success of the proposed regulations. Overall, there appear to be too many unworkable or unclear aspects of the regulations at this time. Our comments and recommendations for clarification follow the sequence of the proposed regulations.

"Categories of Drugs to Be Included Under the CAP"

- The proposed rule states that "the primary site for delivery of drugs is the physician's office." (pg21)

  Comment: physicians often maintain several offices within a geographic area. Current CAP information flow does not include office location in addition to all patient information in order for the drug (s) to be in the correct location. Should a patient change their appointment from one office location to another after the drug has been ordered and shipped, the physician will require a transportation system for the drugs for that patient. Transporting the drug across town without adequate safe guards could compromise the integrity of the drug(s). This could be compensated for by eliminating the ability for the patient to change appointment locations, but then the patient's access to care is also limited. This

could also be accommodated by delivering the drug to the patient's home and having them bring it with them to the physician's office—however the statute prevents delivery by the vendor to any location but the physician's office (Under Statutory requirements concerning claims processing pg 44).

CMS should assure that the final rule contains specific provisions and instructions for physicians with multiple office locations.

- Phasing in by specialty.

  Comment: Oncology is the most drug intensive of the specialties mentioned in the document. The CAP system represents a dramatic shift in financial risk and delivery systems as compared to the current market systems. Additionally the CAP program will be implemented concurrently with Part D market changes.

  CMS should select a small specialty to begin this program and also limit implementation to geographic area (s) that represent both urban, rural and regional physicians.

- Phasing in by specialty.

  Comment: Currently some specialized physicians treat patients from other specialties for infused drugs because the referring physician lacks the staffing or resources to managed complex drug therapies. For example: oncology offices have the staff and resources to manage patients receiving infused drugs. Oncology offices often handle hematology patients because their treatments are similar. Also, neurologist or gastroenterologist may refer patients needing remicade infusions to an oncologist for drug treatment because the referring physician lacks the resources to administer this drug to the patient. CAP proposal states that "all drugs typically administered by an oncologist would be included under this option" (pg 28). This implies that Medicare patients of other specialties that are referred to the oncologist would be included if they are serviced by a physician with specialty code 90.

  CMS should assure that the final regulations clarify the process for referral patients from non-CAP specialty physicians and assure clear reimbursement for the vendor.

- Table 1 Included HCPC codes.

  Comment: We analyzed average profit margins based on ASP plus 6 for the top drugs purchased for 390 oncology clinics in the first quarter of 2005. Of the top 20 drugs purchased by dollars for this group, only 13 were included in Table 1 (pg 31).

  CMS should include all possible HCPC codes for the designated specialty be included in the CAP program to simplify the billing process for physicians and allow vendors to maximize volumes.

- Regarding NDC's bid for HPCP codes.

  Comment: For multi-source drugs, the vendor is only required to bid one NDC. The CAP program lacks a clinical team to evaluate the efficacy of the proposed NDC and puts clinical decisions in the hands of the vendor. We recommend CMS implement a clinical oversight and review team (like the Part D PDP's are required to have) to assure that drugs are selected based on criteria other than cost.

  If there is no clinical oversight, then we recommend that CMS simplify the process for "dispense as written" option or consider other alternatives for the physician that accommodate clinical differences among patients receiving the same treatments.

  Without adjustments to this process, if the physician is forced to use only the NDC bid, then the patient's care may be compromised and the Medicare patient served by the CAP physician may receive a poorer quality of care than the Medicare patient whose physician is not restricted to this "formulary" methodology. In effect, the Medicare CAP patient is potentially discriminated against without their knowledge (unlike Part D where the patient proactively enrolls in the program and can examine the formulary lists by various vendors).

  CMS should implement a clinical oversight process to assure that Medicare CAP patient care is not compromised for multiple source drugs. This clinical oversight process should include outcomes comparisons between CAP and non-CAP patients to assure care is consistent for all Medicare patients. These results should be made public and proactively sent to vendors and physicians.

- Timing for Physician Election (pg 33)

  Comment: Fall, 2005 seems an unrealistic time frame to allow for the specialty to be selected, vendors to have adequate time to bid, bids finalized, materials sent to physicians and beneficiaries notified. Physicians will need time to evaluate the specific NDC's bid from the various vendors and determine which vendor most closely meets his clinical needs. This system represents a dramatic shift in the current process for Medicare patients.

  CMS should either begin with a small specialty, a small geography or adjust the timeframe for selection to be later in 2006.

- The Secretary's authority to exclude drugs that do not provide a financial benefit to the system.

  Comment: We fully support the statement that "we do NOT propose to rely at this time on the Secretary's authority to exclude". If a drug(s) are excluded from a list of potential drugs for a given therapy, then the physician must bill a part of the patients drugs through the CAP system (inclusive of other potential billing options for dispense as written and emergency drugs) and the other part of the non-CAP drugs through the current ASP model. This will also require the physician's staff to manage another inventory for each patient. We believe it would be

administratively and functionally unworkable to exclude a sub-category of drugs within a specialty.

The final regulations should require the physician to obtain ALL drugs for ALL HCPC within the designated specialty for ALL their Medicare patients in order to increase billing accuracy and reduce inventory and paperwork administrative problems for physicians.

"Competitive Acquisition Areas"

- Competitive Acquisition Areas.

  Comment: The use of a "prescription number" to track and bill implies the need for a pharmacy.

  The Competitive Acquisition Areas should follow state lines since pharmacy regulations vary by state.

- National Acquisition Area.

  Comment: The oncology market is currently served by a limited number of specialty distributors (approx 6). Applying a national acquisition strategy, especially one that includes the US territories, will likely decrease competition rather than encourage others to enter a market with low margins and poor cash flow (further reduced cash flow due to the CAP reimbursement strategy). We are concerned that, with even less players in the market, the free-market affect that CMS desires will not occur.

"Statutory Requirements Concerning Claims Processing"

- Medicare can only make payments to the vendor.

  Comment: This requirement eliminates the possibility of the vendor subcontracting with a local or state licensed pharmacy, unless in a fee for service arrangement, since that pharmacy could not be reimbursed directly. Therefore, the vendor must obtain a license in each state and this could add overall cost to the system.

  CMS should allow billing from authorized pharmacies within the vendor's network.

- Adjustments to payments (pg 43).

  Comment: If the vendor is only reimbursed after the drug is administered to the patient, then no payment adjustments would be required for payment to the vendor for drugs not administered (unless CMS implements some type of advance payment, for which adjustments are well specified.)

CMS should remove this reference from this section or clarify further the possible circumstance for payment adjustments for drugs delivered but not administered without any prepayment provisions.

- Written order and physician flexibility (pg44).

  Comment: The statute does not "require" the physician to submit a prescription for individual treatment; however the procedure for billing requires an individual prescription number. Although the proposed rules state that "the term order and prescription are used interchangeably" these two terms have VERY different connotations in the market. An "order" would imply a distribution system. A "prescription" implies the need for a pharmacist and complex pharmacy regulations. This aspect of the proposed rules is unclear and has been the subject of much debate among various parties we consulted with to prepare these comments.

  Also, the statute does not "change a physician's flexibility" for a course of treatment—however if the vendor only bids one NDC per HCPC, then the physician's flexibility (and thus the quality of care to the patient) are automatically restricted.

  CMS should designate this program to be either a pharmacy program or a distribution program and use consistent language within the regulations. If CAP is a pharmacy program, requiring a prescription, the statute will be violated.

  CMS will also need to clarify how one NDC per HCPC code is not violation of the aspect of the statute that preserves physician flexibility.

- Resupply of drugs administered by the physician (pg 45).

  Comment: The process outlined for the physician to demonstrate an unplanned need is cumbersome and unrealistic. It further reduces the physician's flexibility in treating patients when any number of unforeseen circumstances can occur.

  CMS should simply the procedure for the physician to demonstrate an unplanned need by either allowing this need to be billed through the current ASP model or developing an expedited billing process for these drugs to be replaced by the vendor and billed through CAP

- Implications of CAP on physician inventory practices for non-CAP patients

  Comment: CAP requires the physician to use a specific vendor for his Medicare patients, but he is free to use other vendor(s) for other payer types (Medicaid, private pay, etc.) The physician will need at least 3 inventory areas and must have systems to assure that the products are not intermingled. He will retain is current inventory system from one or multiple vendors (most oncologists use at least 2 distributors); He will require a second area that stores shipped CAP orders for each patient while awaiting for the patient to arrive for treatment (and these orders will need to stay clearly separated for each patient); he will require a

3rd inventory of "emergency" for the CAP drugs needed that could not be predetermined.

We believe these multiple inventories and the systems required to manage these inventories will place an unacceptably high new requirement and cost burden on the physician's office. Additionally, we are concerned that multiple inventories will increase claims errors and increase the risk for medication errors by having drugs from various programs in multiple places. Physicians may require office remodeling to accommodate these inventory systems. Certainly new procedures will be required and staff training to manage the CAP program and keep it separated from non-CAP patients.

The increased cost of operations could easily offset any savings to the physician on lost revenues in the ASP methodology.

"Claims Processing Overview"

- Generating the prescription or order number

  Comment: The current processed described is not specific regarding how the prescription or order number is generated or attached to the drug. For oncology, many drugs may be used during the course of a treatment. The process also does not specify if the prescription number is one per patient or multiple prescription numbers (one for each drug) for each patient.

  If the system uses the same prescription for multiple drugs/HCPC codes and the physician does not use all the drugs shipped from the vendor, then the claims matching program will need to match the two orders at the HCPC code level. This would seem to generate many claims errors and thus further delay the claim payment to the vendor.

  The system should incorporate a combination of a unique patient identifier with a separate prescription or order number for each drug the patient requires (like the Part D or any other drug program). This number and corresponding patient information should be attached to each drug for that patient to prevent medication errors and inventory problems.

- Prescription vs. order number

  Comment: Again, it is unclear if the prescription or order "number" is the equivalent of a prescription requiring the drug to be mixed and ready for patient use and therefore is subject to state pharmacy regulations. If this is the requirement, then these "orders" must follow state pharmacy regulations.

  If this "number" is simply a patient numbering system, then the word "prescription" should be removed from the regulations so that a pharmacist and state pharmacy regulations are not required. Then the program and bidding vendor would only be subject to drug distribution regulations

- Verifying Patient Eligibility

  Comment: The ordering process does not include a procedure for the vendor to verify the patient's eligibility for Medicare. Vendors will need access to and their procedure will require eligibility verification before the order can be processes.

  CMS should assure the CAP program includes methodology and technology for the vendor to verify patient eligibility on Medicare.

- Ordering and Billing Units

  Comment: If the CAP system is not a pharmacy program, then the vendor will ship and bill in NDC units. If patient billing occurs in HCPC code units the claims matching software will need to convert the claim to NDC units in order to match to the vendor claim.

  CMS should specify that bidding, ordering and claims processing systems use the same unit of measure—either the NDC or HCPC code units; but not both.

- Increased Billing Operations for Physicians

  Comment: The system would seem to increase the billing process for the physician. The physician will need to include the prescription number for each HCPC code in addition to the HCPC code and quantities when required. The physician will need a separate billing process for any emergency or unplanned drugs (pg 53). Also, the prescription number will need to be created "after the fact" for emergency drugs—this may constitute diversion or fraud according to some state pharmacy laws. Third, the physician will need yet another billing process for Furnish as Written patient billing (pg 53).

  CMS should assure all aspects of the billing system (for all various inventory and drug acquisition options) can be accommodated through a single billing process. Without a simplified approach, the increased costs of the CAP billing system could (especially in combination with the inventory management costs) could outweigh any potential savings on the cost of drugs.

- Lack of aligned incentives.

  Comment: In the current ASP model, the physician has an incentive (getting paid) to process a timely and accurate claim. The CAP program shifts all financial risk to the vendor (the claim must match exactly and co-pays not collected until after the entire claim is processed) without any opportunity for the vendor to control the timing and accuracy of the claim that generates the revenue stream.

The distribution and prescription mail order industries are low margin businesses. A portion of their profitability is derived from payment terms, high volumes and predictable drug use. Alternatively, the alternate site pharmacy's low margins are caused by the significant delays in reimbursement—many pharmacies have outstanding payment days averaging 80 or higher.

The CAP program combines the worst of both current systems—low margins and extended delays in payment—in anticipation of lowering pharmaceutical costs. No aspect of the CAP program addresses the manufacturer's prices to the market or the high cost of biotech drugs.

CMS must provide vendors additional safe guards and financial compensation to address inaccuracy in physician order and claim processing, delays in payment and the unprecedented delay in collecting co-pays and/or third party insurance.

- Collecting Co-pays.

  Comment: The statute requires that copays and third party insurance cannot be collected by the vendor until after the entire claim is processed (pg 45 & 51). In all other aspects of healthcare, copays are collected up front prior to the patient receiving medication or service. If the patient is unable to pay, arrangements are made between the physician and the patient at the time or during service. Vendor collection of copays will require a separate accounting system for the vendor to generate co-pay invoices based on payables or claims notices from Medicare (pg 52).

  Additionally, beneficiaries actively sign up for various programs and are aware (or have motive to be aware) of how the program functions and what their financial responsibilities are. In the case of CAP patients, they will be unaware of the CAP vendor and their role. While the regulations outline some programs for notifying patients, this will only make sense for patients when they need the service. For oncology patients, who may be devastated by the news of their diagnosed condition and are absorbing a lot of information, this communication of a financial obligation from yet another vendor will likely not be understood.

  CMS should go further to assist the vendor in collecting co-pays. The regulations should assist the vendor with collection of co-pays if the patient has expired. Unlike 3rd party insurance, the vendor will be writing this off or trying to collect from the deceased beneficiary's estate.

- Regarding Furnish as Written.

  Comment: Without limits, if any of the vendor's NDC's are perceived to be clinically less desirable, the Furnish as Written provision allows the physician to use any drug desired and split his orders among several sources thus depleting the potential volume to the vendor. Additionally the physician will require yet another billing process for Furnish a Written.

CMS should assure the claims processing system easily accommodates Furnish as Written without delaying payment to the vendor. CMS should also monitor the frequency and clinical need for Furnish as Written through a clinical oversight process. Also, the regulations should include provisions for the vendor to address the physician who may overuse the Furnish as Written to bypass designated NDC's and thereby increase costs to the vendor.

- Order information required:

  The order information should include NDC to assist with matching and appointment location if the physician practices in multiple locations.

- Many Claims for One Patient.

  Comment: The patient could potentially have 3 claims for one course of treatment: the standard order from the vendor, an emergency claim and a furnish as written claim.

  The final regulations should specify how the local carrier will differentiate and pay a CAP patient with multiple claims. This claims processing system should not be more complex or expensive than the current system.

- Patients Transitioning to Medicare.

  Comment: The regulations do not specify how a patient transferring from private pay to Medicare (newly eligible) during a course of therapy will be handled. If the patient is in the middle of treatment (especially for oncology treatment that extends over a period of time), the patient's therapy may change because the CAP vendor NDC's are different from what the patient was receiving under prior coverage.

  CMS should include provisions for the patient transitioning into Medicare during treatment so that the transition does not compromise the patient's current course of therapy.

- Unused Drugs (pg 60).

  Comment: If the CAP program is a pharmacy system (using a prescription or patient label attached to an individual vial or bottle) it is unlikely that state pharmacy regulations will allow a drug to be returned to the vendor and reissued to another patient. Currently, the physician uses drugs from his own inventory so if something is pulled from inventory but not used, it is returned to the shelf without any paperwork requirements. Unused drugs are only returned to a distributor in original packaging and typically are in cases or boxes containing multiple units. For the physician to keep the drug and re-issue it to another CAP patient will be yet a 4th administrative task that has much opportunity for error and would be considered drug diversion in many states.

We believe that the return of unused drugs is UNworkable under any circumstances unless in the original case or box and without ever having patient labels attached. The return drug aspect of CAP leaves many parties in the industry vulnerable to drug diversion. Approximately 11 states allow for the "reuse" of unused drugs (usually only oral solids) under very specialized circumstances. Typically, unused drugs that have been originally dispensed for a patient are destroyed by a qualified nurse, pharmacist or administrator. CMS should remove any reference to the return of unused drugs dispensed to the patient so as to avoid implying that state pharmacy regulations can be ignored. Furthermore, vendors should be allowed compensation for these mis-ordered drugs and any drugs that are partially used or prepared in error and unused by physician staff.

- Claim Errors (pg 61)

  Comment: The vendor is penalized for claim errors made by the physician.

  CMS must provide vendors additional safe guards and financial compensation to address inaccuracy in physician order and claim processing that will lead to payment delays, delays in collecting co-pays and/or third party insurance. Regulations need more stringent requirements for physicians to comply including financial penalties for excessive errors.

"Contracting Process—Quality and Product Integrity Aspects"

- GPO's as potential bidders (pg 76)

  We have carefully evaluated the CAP proposal. As a GPO, our function in the market is to develop contracts and assure pricing and contract terms to our members. Members (pharmacies or physicians) often belong to multiple GPO's and use multiple distributors. Likely bidders in this program will be either specialty distributors, PBM's who currently have a distribution arm or large national pharmacy chains. The bidder will need to have at least one major component of the system in their current operations and financial model: patient billing programs and claims systems (and a business model that can be profitable with high outstanding receivables) and/or product distribution systems (and a business model that is profitable on very slim distribution margins).

  As a GPO, we currently operate under both financial models: long-term outstanding receivables and low operating margins. However, we lack both business processes of drug distribution and patient claims processing and collections. The cost of entry into CAP would overwhelm any potential revenue stream.

  We do have a national network of member pharmacies who could bid on this program. Our members have indicated that there are too many unworkable

aspects of the program (especially billing, timing of collecting copays) to participate. In running profitability models for pharmacy participation, especially for oncology, we find potential profit margins of approximately 3% under the current ASP plus 6 methodology. Our pharmacy network would need to bid with even lower margins to be considered in the program. In their opinion, the financial risks and increased operating costs far outweigh any benefits to the program and would likely cause these pharmacies to operate at a loss for Medicare Part B patients.

Should the revised regulations adopt recommendations that lower implementation costs, simplify processes and clarify legal responsibility for drugs in a manner that our national network of pharmacies finds acceptable, our network has agreed to re-evaluate their position and would consider bidding in the CAP program.

"Dispute Resolution"

- Vendor Losses.

  Comment: Currently vendors can monitor their acceptable losses through payment history and credit ratings. A vendor can pre-assess their risk. Under CAP, vendors cannot pre-asses their risk based on the physician's history of claims processing.

  When the geography and physician specialty, CMS should provide bidding vendors with some type of claim history for each potential qualifying physician that will assist bidding vendors in assessing heir financial risk prior to finalizing their bid. In addition, the regulations should specify an acceptable loss or allow vendors to specify an acceptable threshold within their bid.

- Product Integrity.

  Comment: If CAP is a pharmacy program (using a prescription and requiring a pharmacist) then drugs that are mixed patient ready and stored must currently comply with USP<797>

  CMS should include <USP797> in this section of the CAP regulations.

- Code of Conduct

  Comment: The code of conduct and conflict of interest requirements are very thorough and we commend CMS for including these requirements. We are already hearing about agreements between manufacturers and potential vendors to bid their products and the manufacturer will reimburse the vendor for any losses on the bid.

Currently, the GPO's provide an objective 3rd party to monitor and prevent conflicts and assure some equity within the market. The CAP program eliminates the GPO entirely and places accountability with the government to monitor this. We expect that the government will actively monitor this aspect of the program or could engage a 3rd party to assure that all rebates and financial deals are equally reported on a regular basis.

"CAP Bidding Process"

- Exclusion of Waste Spoilage, etc in the Vendor's Bid

  Comment: In the current system, especially in oncology, physician's nursing and technical staff is primarily responsible for preparing the drug for administration. In oncology, patients are tested on site just prior to treatment to determine the dosage of certain drugs and assure they can receive the treatment. It is in the best interest of the physician to assure his staff limit mistakes that cause drugs to be wasted or unused, since any wasted drug is included in his cost. In addition, (although a questionable practice without a pharmacist involved) partial vials of unmixed drugs are stored and saved for use on another patient.

  Under the CAP regulations, the vendor cannot include any costs for waste or partial use of drug within the bid (pg 92-93). In this system, the physician has no incentive to assure that his staff thoroughly examines patients before drugs are prepared. Also, partially used vials cannot be re-assigned to another patient within the CAP program. Finally, the physician has no way of calculating dosages of some meds until the patient arrives, so the vendor must ship and pay for the entire vial. Billing and claim errors will be increased.

  We believe that the CAP system will increase wasted drugs, especially in oncology. CMS should allow vendors monitor wastage by physician and be compensated for physicians with excessive problems.

- HCPC weighting calculation

  Comment: The list in Table 1 was generated from 2003 data. Our Q1-05 purchases indicate that 7 of the top 20 purchased drugs by dollar were not represented among that list. New drugs and therapies arise frequently (especially in oncology).

  The weighting system should reflect the prior quarter's HCPC volumes and be re-evaluated each quarter or each period that prices are adjusted.

- Additional costs for HCPC codes.

  Comment: Some HCPC codes require additional drugs and supplies that will not be part of the NDC for that HCPC code. We assume that the physician must acquire these products (such as IV's, needles, syringes, anti-inflammatory drugs, OTC's, etc) and have the cost of these drugs covered in their administrative fee.

The bid process should include the entire list of HCPC codes for that specialty along with weighted volumes for the prior quarter. CMS should also specify the unit, HCPC code or NDC. Also, CMS should specifically outline to physicians the process for being reimbursed for additional products and drugs required that are not part of the HCPC codes.

- New Drugs, Patent Expirations, etc.

  Comment: When new drugs are introduced and patents expire, the market shifts rapidly. In the case of MGI's release of Aloxi, a new anti-emetic, we saw the market shift significantly (35%) within 3 weeks of the drug released to the market. Vendors could be significantly disadvantaged if the adjustments are not made at least quarterly.

  Adjustments for new products, patent expirations, should occur at least quarterly. New drugs should be included at WAC plus 6% (like the ASP methodology) until the following bid cycle when they can be equally bid across all vendors.

"Physician Election Process"

- The Possibility of Multiple Vendors by One Physician

  Comment: Point #4 (pg 115) indicates that the physician may select multiple vendors—all prior aspects of the regulation indicate that all physicians within the group must select ONE vendor for all Medicare patients. Allowing multiple vendors will require physicians to maintain separate emergency and patient inventories for EACH vendor. Multiple vendors also increases the chance for claims errors which will increase disputes and decrease cash flow for vendors. Multiple vendors also will cause significant confusion for beneficiaries who could then receive bills for co-pays from multiple vendors.

  CMS should require the physician to select only ONE vendor for ALL Medicare patients for ALL drugs within the specialty. This segment of the regulations should be clarified.

- Physicians Pick and Choose within the Drug Category

  Comment: Point #4 (pg 115) also implies that the physician can select the drug categories in which they choose to participate. All prior references in the regulation state that ALL HCPC codes within the physician specialty (or as otherwise selected by the Secretary) must be acquired through the CAP vendor.

  We believe that it is UNworkable to allowing the physician to select from within the list of drugs. The inventory, ordering and billing complications will be unmanageable for all parties.

CMS should assure that all aspects of the regulations are consistent with regard to drugs within the category. CMS should NOT allow physicians to select only some drugs within a drug category.

- Beneficiary Education.

  Comment: Not all Medicare patients will receive treatments through the CAP program. If CMS notifies patients in advance, they will be confused about a benefit and change in co-pay processes that may not apply to them. They may use a physician that does not participate in CAP. Or, the CAP process will not apply to them until they are diagnosed with a related illness covered under the program. They may think they need to sign-up for one of the vendors, like the Part D program, especially since the programs are being implemented concurrently. Proactive communication to beneficiaries for a service they may not use will likely increase cost to CMS and physicians to address questions from patients for which the program may not apply to.

  Alternately, waiting to notify patients until they are diagnosed with a related disease will add stress to their condition and likely not be well read or understood at the time. Since the system will vary between patients, beneficiaries who likely compare notes with friends and relatives will have accurate, but conflicting information. The burden of communication will realistically fall to the vendor who must collect co-pays from the individual.

  While there is no easy solution to this problem, CMS should adopt a process that assists the vendor in collection of copays since they are financially at risk and or compensates them financially for unpaid co-pays in the form of increased bid prices.

- Physician Inventory.

  Comment: Page 122 indicates the physician must maintain an electronic or paper inventory for CAP drugs. Maintaining an emergency inventory and inventory tracking for each patient is unrealistic and will add significant administrative time to physician's staff. Most physicians do not maintain sophisticated inventory systems and this requirement would likely be ignored, understaffed or be done incorrectly. Implementing this type of system will add costs to the physician's office overhead.

  CMS should require the vendor (who is professionally equipped for this type of program) to provide this system to the physicians and compensate the vendor within the bid prices.

"Regulatory Impact Analysis"

- Impact to Small Businesses.

  Comment: We represent a large number of independent pharmacies. In their opinion, they are unable to participate in this program because the only possible entities with the financial resources are large corporations currently distributing in this market. Therefore, the statute eliminates the possibility for a local pharmacy to work directly with physicians to reduce costs while improving patient care in these areas. Additionally, the regulations prevent delivery and reimbursement in any other setting (pg 43), so, even if financially beneficial, providers in ambulatory infusion centers or home care infusion providers are automatically restricted from this market.

  CMS should re-evaluate the analysis for impact to small businesses and other entities including independent pharmacies.

- Legal Ownership of the Drug.

  Comment: Page 130 indicates the physician does not take "legal ownership of the drug. The regulations state: "because the drug remains the property of the vendor until the time of administration" means that the physician could tamper with, dilute or resell the drug and not be held liable for this or other illegal activity. It could also be implied that the vendor is legally responsible for all aspects of the drug, including clinical mixing and administration by physician staff. This legal responsibility must reside with the person who takes possession of the drug.

  It is Unworkable for the vendor to be fully responsible for the drug until administration. For the vendor to be fully responsible, he would need to pick, ship, mix and administer the drug to the patient.

  While it will be true that the physician does not directly pay for the drug, CMS must clarify this reference to legal responsibility for the integrity and dispensing of the drug following receipt in the physician's office, mixing and administration to the patient.

- Drug Access Issues to Beneficiaries (pg 132).

  Comment: We believe the CAP program, in its current form will could provide a lower quality of care or deny access to care for beneficiaries whose physicians use the CAP program. Additionally, since the physician chooses the program, not the beneficiary, this aspect of their care is imposed upon them without their consent. Our concerns regarding quality of care are related to the restriction of one NDC per HCPC code, delayed access to new drugs, and lack of clinical oversight in the program.

  CMS should conduct a full clinical outcomes study at least every 6 months comparing outcomes and drug delivery of patients with same diagnoses within and outside of the CAP program. The results of this study should be provided to all beneficiaries so that they may select physicians who do not use the CAP program if they desire. Alternately, CMS could allow the

beneficiary to be the final decision-maker regarding whether the physician uses CAP or ASP prior to treatment.

* * * * * *

PBI welcomes the opportunity for further dialogue regarding these issues and would be pleased to provide any additional information you may require. Please feel free to contact me at 800-395-9495 if you have any questions.

Sincerely,

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SPECIAL COMMITTEE ON AGING

April 18, 2005

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Administrator
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2005 APR 20 AM 11:19

Dear Administrator McClellan:

As the Centers for Medicare and Medicaid Services (CMS) implements H.R. 1, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, I urge you to consider exempting blood clotting factors and alpha-1 proteinase inhibitors from competitive acquisition under Medicare Part B. Failure to address this issue could limit access to and choice of lifesaving plasma derived and recombinant analog therapies for persons with hemophilia and Alpha-1 antitrypsin deficiency, also known as genetic emphysema.

CMS should fully evaluate excluding blood clotting factors and alpha-1 proteinase inhibitors from the definition of "competitively biddable drugs and biologicals" in Section 1847 A (a) (2) (A) of the Social Security Act (SSA). Individuals with hemophilia and alpha-1 need uninterrupted access to these lifesaving therapies. Patients and their advocates are concerned that the competitive acquisition program would not provide unfettered access to all brands to treat these conditions. As evident in initial drafts and consideration of H.R. 1, there was consensus that competitive acquisition, although intended to reflect market dynamics, may not be workable for blood clotting factors.

Section 1847 B (a) (1) (D) of the SSA gives the Secretary exclusion authority to exempt competitively biddable drugs and biologicals from the competitive acquisition program if bidding for such drugs or biologicals is not likely to result in significant savings; or is likely to have an adverse impact on access to such drugs or biologicals. Based on these criteria, the Secretary could use this exclusion authority to exempt blood clotting factors and alpha-1 proteinase inhibitors from the competitive acquisition program under Medicare Part B.

It is important that individuals with hemophilia and Alpha-1 have access to therapeutic options. For persons with hemophilia who infuse blood clotting factor on a regular basis to replace absent proteins, the ability to choose which therapy works best for them is an important component of their treatment regimen. The same holds true for persons with Alpha-1. In addition, blood clotting factors are not interchangeable; some are derived

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SCRANTON, PA 18503
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from human plasma, while others are recombinant and created from single cells. Physicians and patients should jointly make the determination on what is the most efficacious therapy.

Thank you for your attention to this matter.

Sincerely,

Rick Santorum
United States Senate

RJS/jv

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ASSOCIATION OF NORTHERN CALIFORNIA ONCOLOGISTS

State/Regional Affiliate, American Society of Clinical Oncology • Member, Association of Community Cancer Centers
Member, National Coalition for Cancer Survivorship
Partner, California Oncology Consortium • Member, Hematology Oncology Leadership Network

APR 25 2005

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April 22, 2005

Centers for Medicare & Medicaid Services
Attn: CMS-1325-P
Post Office Box 8010
Baltimore MD 21244-8010
(via USPS & e-mail)

Ladies & Gentlemen:

Below (attached if read via e-mail) are the *Association of Northern California Oncologists* (ANCO) comments on **CMS-1325-P, the proposed *Competitive Acquisition Program* (or CAP) for Medicare Part B drugs.**

By way of information, the *Association of Northern California Oncologists* (ANCO) was organized in 1990 to be an advocate for, educate, and inform the practicing medical oncologist and hematologist and currently represents approximately 260 medical oncologists and hematologists throughout Northern California. While the majority of our members are community-based physicians, ANCO also represents the medical oncologists of the regional academic cancer centers—*Stanford University, UC Davis*, and *UC San Francisco*. We serve the needs of our physician members, their nurse and practice managers, and their patients.

ANCO is a member of the *Association of Community Cancer Centers* (ACCC), a state/regional affiliate of the *American Society of Clinical Oncology* (ASCO), a partner with the *Medical Oncology Association of Southern California* (MOASC) in the *California Oncology Consortium* (COC), a member with several other state oncology and oncology practice manager societies of the *Hematology Oncology Leadership Network* (HOLN), and a member of the *National Coalition for Cancer Survivorship* (NCCS).

ANCO is dedicated to assisting oncologists and their staffs deliver the highest quality patient care by providing a forum for the exchange of ideas, data, and knowledge and by representing the interests of

oncologists and their patients before state and federal government agencies, regional and national oncology and medical societies, and insurance and pharmaceutical companies.

ANCO's comments represent the opinions expressed by its physician *Board of Directors* as well as their practice pharmacists, nurses, and administrators.

In general, ANCO favors a system where medical oncologists are not dependent on the purchase and sale of drugs in order to survive. Running a medical oncology practice that is always hundreds of thousands of dollars in debt is inefficient and stressful. Rather, medical oncologists want and need to be reimbursed for their professional services as highly trained specialists and for the services they, their pharmacists, and their nurses provide to people with cancer.

Unfortunately, while Medicare's new drug reimbursement system makes it advisable for medical oncologists to remove themselves from drug purchasing and sale on behalf of their patients, Medicare's proposed *Competitive Acquisition Program* (CAP) is not a viable alternative for many reasons. Specifically:

- CAP's unique logistical and tracking requirements make it untenable and unworkable, especially given that medical oncologists would need to maintain their current buy-and-bill systems for private payers in parallel. Adding a new drug acquisition system to medical oncology practices is an unacceptable administrative, logistical, and coding/billing burden. For example, ANCO member practice experience with the provision of drugs through outside vendors in the private/commercial market finds that drug delivery is haphazard and often delayed.

- the proposed CAP rule does not specify how drugs are to be delivered to practices, who will take responsibility when the inevitable snafus occur, and how physicians will be reimbursed when physicians are forced to use drugs for Medicare beneficiaries from their own inventories.

- CAP vendor contracts are to be let for three years. This would allow incompetent CAP vendors to remain in business far too long. On the other hand, letting CAP contracts annually and potentially changing CAP vendors annually is equally unacceptable. Most medical oncology practices establish long-term relationships with their drug distributors in order to maximize economies and efficiencies.

- CAP vendors (i.e., drug wholesalers, drug distribution centers, and drug distributors) would dispense drugs and be reimbursed for patient services unlawfully as only a pharmacist or a licensed pharmacy may dispense a prescription to a specific patient.

However, if CAP is to be initiated in 2006 and if it is intended to impact medical oncology, then the following must occur:

- CAP must be national, not regional or geographical.

- CAP must cover all drugs used in medical oncology including antineoplastics and supportive care drugs (i.e., antiemetics, growth factors, and antibiotics). New drugs must be included as soon as they are available.

- CAP vendors must fill all physician orders for all drugs regardless of the CAP vendor's past experience with a patient regarding payment or their concern about coverage for off-label use. In addition, CAP vendors must not be allowed to require patients to sign *Advance Beneficiary Notifications* (ABNs) before they release drugs to the physician for a specific patient.

- CAP prescriptions must not require the patient's age, height, weight, or other irrelevant information.

- CAP vendors must not act as pharmacists or prescription benefit managers. Despite the fact that CAP vendors may employ pharmacists, their responsibility must be limited to sending ordered drugs to the ordering physician. In addition, CAP vendors must be prohibited from exercising the responsibilities of a physician or pharmacist with regard to drug interactions, appropriate dosing, or other issues that impinge on physician responsibilities. Finally, CAP vendors must be prohibited from providing therapeutic substitutions for ordered drugs to the ordering physician. In summary, CAP vendors must not be allowed to dictate what physicians can or cannot do for their patients. They must not be allowed to behave any differently than other drug wholesalers, drug distribution centers, and drug distributors with which physicians have existing relationships.

- CAP vendors must carry substantial liability insurance and indemnify physicians for any losses they incur on the basis of the CAP vendor's negligence, errors, or omissions in filling physician drug orders.

- CAP vendors, not participating physicians, must track the ultimate use and/or disposition of unused drugs.

- physicians will incur additional administrative costs if they participate in CAP given its novelty and the fact that it must be done in parallel with existing buy-and-bill drug acquisition for commercial payers. Therefore, an additional administrative fee must be made to physicians to reimburse for these additional administrative costs.

• physicians must have the right to either chose another CAP vendor or opt out of CAP if their CAP vendor declares financial insolvency or proves incompetent during a the contracted year.

• any transfer of financial risk from the participating physician to the CAP vendor must be complete leaving absolutely no liability or penalty to the participating physician. For example, the risk of post-payment denial of claims for off-label use of drugs is a risk that medical oncologists have willingly borne in the best interest of their patients. Under CAP, this is a risk that must be accepted in full by the CAP vendor. They must not have the right to complain to CMS or local Medicare carriers about the drug ordering patterns of specific medical oncologists or to pressure physicians to alter their prescribing patterns. To do so would be an unacceptable intrusion on the independence of physician clinical decision making on behalf of his/her patient.

• Ambiguous terms/phrases in the proposed rule must be clarified. For example, *emergency situation* leaves the door open for an interpretation of a qualifying emergency that would be so restrictive as to negate the safeguard that is clearly intended.

Exceptions are to be allowed for situations where *a specific formulation* is needed that the vendor does not supply. This may be a good thing, but what exactly is *a specific formulation* and will this allow CAP vendors to not carry certain drugs if they find that CMS is not paying the vendor enough to cover their costs?

A physician must notify the CAP vendor if a drug is not administered *on the expected date of administration.* In reality, medical oncologists often delay administration by a week for low blood counts or failure to completely resolve the toxicities of a previous chemotherapy cycle. This notification requirement would be too burdensome if a medical oncologist had to add the CAP vendor notification to an already long list of things to do.

Thank you for the opportunity to comment on CMS-1325-P, the *Competitive Acquisition Program.*

Sincerely,

Peter Paul Yu, M.D.
ANCO *President*

Johnson & Johnson

[redacted] 111

KATHLEEN A. BUTO
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APR 26 2005

April 26, 2005

By Hand Delivery

Mark B. McClellan, MD
Administrator, Centers for Medicare and Medicaid Services
United States Department of Health and Human Services
Attn: CMS-1325-P
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B (CMS-1325-P)

Dear Dr. McClellan:

On behalf of Johnson & Johnson (J&J), we are providing the following comments and recommendations in response to the proposed rule issued by the Centers for Medicare and Medicaid Services (CMS) regarding implementation of the Competitive Acquisition Program (CAP) for Part B drugs and biologics. 70 Fed. Reg. 10746 (March 4, 2005).

J&J is the world's most comprehensive and broadly based manufacturer of health care products, as well as a provider of related services, for the consumer, pharmaceutical and medical devices and diagnostics markets. J&J has more than 200 operating companies in 57 countries around the world employing approximately 109,000 employees and selling products in more than 175 countries. The fundamental objective of Johnson & Johnson is to provide scientifically sound, high quality products and services to help heal, cure disease and improve the quality of life. Of particular relevance to this rulemaking, J&J operating companies manufacture and market some of the most important drugs and biologics covered under Part B of the Medicare program, including PROCRIT® (epoetin alfa), REMICADE® (infliximab), RISPERDAL CONSTA® (risperidone) and NATRECOR® (nesiritide).

J&J's overarching goal with the CAP program is to ensure that Medicare beneficiaries have meaningful access to Part B medical therapies. We believe the CAP can help ensure patient access to important therapies while offering an alternative for physicians to the current "buy and bill" system where physicians purchase the drugs, collect the beneficiary coinsurance and bill the Medicare program for drug reimbursement. We urge

CMS to implement the new CAP program with beneficiaries' access to care as its top priority.

Our specific comments and recommendations follow. As requested by CMS, we have organized our comments consistent with the order they appear in the preamble to the proposed rule. We have also included recommendations on policy issues that are related to, but not directly addressed in, the proposed rule.

I. Categories of Drugs to be Included under the CAP

Section 1847B(a)(1)(B) of the Social Security Act (SSA) gives CMS the authority to phase-in categories of Part B drugs that would be offered under the CAP. CMS has offered three major options in the proposed rule for the types of Part B drugs that would be included in the CAP program for its initial implementation for 2006:

(1) All Part B drugs delivered 'incident to' a physician's service;
(2) Drugs used by a single physician specialty: oncology; or
(3) Drugs administered by specialties that use fewer Part B-covered drugs.

CMS does not propose a specific option for 2006, but rather seeks comment on the three options highlighted above.

J&J Recommendation: We support the inclusion of all Part B drugs delivered 'incident to' a physician's service in the initial rollout of the program in 2006. It is important that all physician specialties be given the opportunity to participate in the CAP and be allowed to choose the categories of drugs and biologicals they want to receive from participating vendors. We oppose any restrictions on the categories of drugs that could limit beneficiaries' access to care. We are particularly concerned that restricted categories could limit access to mental health dugs and complex biologics. If it is not possible to include all Part B drugs in the initial phase-in, we strongly recommend that, at a minimum, mental health drugs and other products such as complex biologic therapies be included in the initial phase-in on January 1, 2006.

A. The Importance of Including Mental Health Drugs in Initial CAP Rollout.
As CMS notes in the proposed rule:

> *"The competitive acquisition program provides opportunities for physicians who do not wish to be in the business of drug acquisition. Engaging in drug acquisition may require physicians to bear financial burdens such as employing working capital and bearing financial risk in the event of non-payment for drugs. The CAP is designed to reduce this financial burden for physicians."* 70 Fed. Reg. at 10748.

We concur with CMS and encourage the agency to ensure access by including drugs and biologics in the CAP for those cases where physicians are not capable of engaging in the practice of drug acquisition. Mental health drugs commonly prescribed by psychiatrists,

especially those used to treat schizophrenia, clearly fall into this category. Most psychiatrists who practice in community mental health centers (CMHCs) have very limited experience with drug acquisition under Medicare Part B. This is due in large part to the fact that the standard of care for the treatment of schizophrenia has been oral atypical anti-psychotics that are dispensed through pharmacies. However, there are several short and long-acting injectable anti-psychotics covered under Part B. In particular, the 2003 approval of RISPERDAL® CONSTA®, the first long-acting injectable atypical antipsychotic, represented a major advance in treatment for people with schizophrenia, most of whom have difficulty complying with a daily medication regimen.

As we presented to your clinical and reimbursement staff at a recent meeting, this new class of therapy, currently represented by RISPERDAL® CONSTA®, has the potential to offer better medication compliance for schizophrenic patients and may lead to fewer expensive inpatient hospitalizations in the Medicare program. Attached for the record is a copy of the slides that were presented to your staff highlighting the clinical benefits of this medication and the difficulties in treating schizophrenia.

Unfortunately many Medicare beneficiaries are unable to access this new product through the ASP + 6% drug acquisition system. As CMS is aware, physicians must make large financial outlays to acquire drugs and biologics covered under Medicare Part B. CMHCs, where a majority of Medicare beneficiaries with schizophrenia access care, are largely non-profit entities and are especially poorly equipped to incur this substantial financial exposure. In addition, they do not have adequate funding to develop the capabilities to support the current ASP + 6% drug acquisition system, including claims tracking and appeals, coinsurance collection and accounts receivable, and enhancements to their current billing systems. As a result, many patients are finding it difficult to access these important new therapies in CMHCs.

Including mental health drugs in the initial phase-in of the CAP would allow psychiatrists and CMHCs to opt out of the current reimbursement system and instead obtain these drugs through the CAP. This would remove a major financial barrier -- thereby ensuring patient access to these important medications -- and allow psychiatrists to concentrate their time on treating the patient as opposed to drug purchasing and reimbursement. As CMS notes, this would fulfill one of the primary purposes of the CAP, which is to "...provide alternatives to physicians who do not wish to be in the drug purchasing and coinsurance collection business." 70 Fed. Reg. 10769. For the reasons stated above, J&J believes it is imperative to include mental health drugs in the initial phase-in of the CAP on January 1, 2006 so that Medicare beneficiaries can access this important new class of therapy.

B. Complex Biologics Should Also Be Included in CAP in 2006. If CMS is unable to include all Part B drugs in CAP in 2006, it should also make complex biologics like REMICADE® (infliximab), for the treatment of Rheumatoid Arthritis and Crohn's disease, and NATRECOR® (nesiritide), for the treatment of congestive heart failure, a priority area. These products typically share the following characteristics:

- They represent a significant cost to any given practice;
- They typically entail coinsurance and deductible collection risks;
- They may also require practices to incur costs to maintain safety stock (e.g., extra vials to be used in the event of wastage/breakage);
- They may require practices to incur opportunity costs of capital available to the practice (i.e., the monetary value tied up in the value of inventory);
- They present a significant reimbursement risk that physicians perceive as not being adequately addressed under the average sales price (ASP) +6%; and
- They are products for which alternate sites of care are not always readily available (e.g, not all hospital outpatient departments may not provide all types of IV or clinic based therapies).

Under the Medicare Modernization Act (MMA), CMS was required to begin paying for Medicare Part B drugs on the basis of ASP +6%. We understand that some rheumatologists, cardiologists and other specialists who infuse these and other complex biologic therapies are not able to cover their costs under the ASP + 6% payment formula. Given these difficulties and the potential for patient access problems, we believe that specialties that commonly infuse complex biologics such as rheumatology, gastroenterology and cardiology should also have the option of CAP in 2006.

C. Categories of Drugs Should Be Comprehensive and Not Single Out Only a Few High Utilization Products. We also support the basic direction enunciated by CMS in the proposed rule on how it intends to structure the categories of drugs to be included in the CAP. These categories should be comprehensive in nature for the given clinical or specialty area (e.g., oncology, non-oncology). CMS should not single out only a few high utilization drugs or biologics in a given category to test out the program in 2006. It would make most sense to allow specialties interested in participating in the CAP to acquire all their drugs from the CAP vendors, and not merely test out a select few. We believe this approach would allow CMS to learn how to best implement the program in the longer term and most efficiently ease the administrative burden on physicians who are interested in relinquishing their buy and bill system duties under Medicare Part B.

II. Competitive Acquisition Areas

A. Structure of the Competitive Acquisition Areas. Section 1847B(a)(2)(C) of the SSA directs CMS to define and designate "competitive acquisition areas" or the geographic boundaries within which vendors will compete for contracts to provide competitively biddable Part B drugs. CMS has identified 3 broad options for defining competitive acquisition areas under the CAP program: (1) a single national competitive acquisition area; (2) regional competitive acquisition areas; or (3) statewide competitive acquisition areas. CMS does not propose a specific option for 2006, but rather seeks comment on these three general options.

J&J Recommendation: To promote patient access to a variety of Part B drugs as well as vendor competition, we believe physicians should have a diversity of national vendor and

smaller vendor options from which to select their drugs under the CAP. For example, large national pharmacy benefit managers (PBMs) may more frequently supply higher-volume medications; whereas some smaller specialty pharmacies may tend to concentrate on lower-volume specialty medications. We believe that a state-based system of competitive acquisition regions would be the most feasible way to allow both larger and smaller vendors to participate in the program. If CMS implements larger regional competitive areas or even a single national competitive acquisition area, it could exclude smaller specialty pharmacies that do not have the capacity to distribute drugs across larger geographic regions. Given that current licensing for specialty pharmacies and vendors operates at the State level, the state-based approach is the most feasible to way to implement the CAP in 2006 and at the same time provide the best opportunity for a combination of national, regional and smaller specialty vendors to participate in the program.

B. Geographic phase-in. Section 1847B(a)(1)(B) of the SSA also gives CMS the authority to phase-in the CAP program on a geographic basis. The proposed rule discusses a number of options (i.e., nationally, regionally or by state) on how to rollout the program geographically.

J&J Recommendation: We prefer nation-wide implementation in January 2006. If this is not possible, CMS should focus on states with the largest metropolitan statistical areas (MSAs) like California, New York, Texas and Pennsylvania so that as many physicians as possible can have the option to participate in the program and expand patient access to medications.

The agency may also want to prioritize certain states like South Carolina, West Virginia and Minnesota that currently have state sales taxes on certain types of office-administered non-oncology drug therapies that can result in a barrier to access. (In other areas, such as Louisiana local parish sales taxes also represent significant obstacles to physicians providing Medicare patients with access to office-based therapies.) For example, in South Carolina, physicians must pay a 5% tax on their non-oncology drug purchases. As a result, physicians in that state will effectively not be paid ASP + 6% for non-oncology drugs purchased because the 5% tax will almost completely offset the 6% "add-on." Faced with lower Medicare reimbursement because of these taxes, physicians may curtail the services they offer, thus reducing patient access to necessary therapies. The CAP system would offer an important option to physicians infusing complex biologics like REMICADE® and help minimize patient access problems in these states.

III. Claims Processing Overview

A. Definition of an "Emergency Situation." Physicians participating in CAP may not always be able to obtain the drugs they need from their vendor in a timely fashion. As a result, there may be instances when the doctor must use medications from his own personal stock for a Medicare patient, and then in turn replace that drug with one supplied from the CAP vendor at a later time. To address these types of situations, section 1847B(b)(5) of the SSA requires CMS to establish rules that allow physicians to re-

supply their own inventories with drugs and biologicals acquired under CAP. Consistent with the statute, CMS has proposed that physicians demonstrate all of the following in such circumstances:

(1) The drugs were required immediately;
(2) The physician could not have anticipated the need for the drugs;
(3) The vendor could not have delivered the drugs in a timely manner; and
(4) The drugs were administered in an "emergency situation."

The proposed rule does not offer a definition of an "emergency situation," but seeks comments on how it should be defined in the Final Rule.

J&J Recommendation: While the statute requires that physicians must demonstrate all four of the above points in order to re-supply their own inventories with products acquired under the CAP, we note that it will be extremely difficult to craft a definition of "emergency situation" that will be clearly distinct from a definition of "required immediately." We encourage CMS to develop an expansive definition of an "emergency situation" that recognizes unforeseen changes in a patient's physical and clinical condition. For example, the required dosage of many biologics is dependent on a patient's weight. If a patient with Crohn's disease on REMICADE® presents himself to the doctor and has unexpectedly gained weight, the required dosage for the medication could be different than that required for the previous treatment. The physician should not have to delay treatment for the patient until additional medication arrives from the CAP vendor.

Rather, the provider should have the ability to increase the required dosage from his or her own stock and provide care to the patient as necessary. Likewise, oncology patients often need supportive care as a result of their chemotherapy treatments and these should be readily available to them should a patient's medical condition change unexpectedly. We strongly believe that CMS' definition of "emergency situation" should take into account a beneficiary's changing health care needs and physical condition. The definition should be crafted in such a way that it will allow a physician to use medications from his/her own personal stock when, in the judgment of that physician, a delay in therapy could increase the risk of an adverse outcome.

B. "Furnish as Written" Policy. CMS is also proposing to allow the physician to obtain a drug under the ASP methodology in "furnish as written" cases when medical necessity requires that a specific formulation of a drug be furnished to the patient. This situation could arise when the vendor has not been contracted to furnish a specific formulation of a drug defined by the product's NDC number.

J&J Recommendation: We support CMS' proposed policy to allow physicians to supply "furnish as written" medications to patients that are medically necessary for patients. We believe this policy is consistent with our over-riding goal for the CAP to ensure access to medical therapies in the Medicare program. If a medication is truly necessary to treat a patient's condition and it not offered by the CAP vendor, the

physician should have the option to receive that specific formulation through the ASP + 6% methodology. Likewise, all NDC put ups should be available from the vendor so that patients have access to the appropriate vial and dosing size.

C. Physician Choice of CAP Vendors. CMS is seeking public comment on whether physicians must obtain all categories of drugs that a particular CAP vendor provides, or whether the physician should be allowed to use different vendors for different categories of Part B medications.

J&J Recommendation: Physicians should not be required to have all CAP-covered Part B drugs come from a single vendor. If physicians would prefer to have different categories of drugs provided by different vendors, they should be granted this flexibility. Some vendors may be more adept at providing certain types of drugs. By giving the physicians the flexibility to select multiple vendors, CAP could improve competition and overall customer service, as well as enhance timely delivery of medications to Medicare beneficiaries.

IV. CAP Bidding Process – Evaluation and Selection

A. 106% ASP Composite Bid and Number of Vendors in Competitive Areas. CMS is proposing to select from all bidders that meet the quality and financial thresholds up to five lowest bidders for a drug category in each area. However, CMS has stated that it would not select any bid from a vendor for a category that is higher than 106 percent of the weighted ASP for the drugs in the category, also described by CMS in the proposed rule as the "composite bid threshold."

J&J Recommendation: We recognize that the CAP may offer the potential for savings to both the Medicare program and beneficiaries through lower coinsurance payments for covered Part B drugs. However, if CMS is interested in creating a vibrant and competitive CAP program in all areas of the country, it may want to consider easing the strict ASP + 6% composite bid threshold in certain areas where there is little or no vendor interest in participation. For example, if only 3 or fewer vendors in a particular competitive acquisition area decided to bid on drug categories covered under the CAP, CMS could increase the overall composite bid limit above 106% of ASP to attract additional vendors. There is nothing in the statute that requires CMS to exclude bids that are higher than ASP + 6% and CMS could still ensure that the overall CAP program results in savings to the Medicare program by limiting the number of competitive areas where the CAP is adjusted. Increasing the number of bidders would expand physicians' options and potentially improve patient access. It would be unfortunate if the proposed composite bid limit discouraged vendor participation and thus denied physicians seeking an alternative to the current drug acquisition system an opportunity to participate in the CAP program.

B. Adjustment of Drug Reimbursement Amounts. Section 1847B(b)(4)(B) of the SSA provides that vendor contracts under CAP must be for a period of 3 years. CMS is proposing to set the individual drug reimbursement rates in the first year of the contract

based on the median bid of the individual drugs from the winning bidders. The agency is then proposing to update the CAP prices on an annual basis for year 2 and year 3 based on changes in the vendors' "reasonable, net acquisition costs" for that category. CMS is inviting comment on the appropriate frequency for these updates.

J&J Recommendation: Although we recognize that there are certain administrative burdens placed on the vendors for supplying CMS with the data necessary to establish the "reasonable, net acquisition costs" for that category, we believe CMS should consider at least bi-annual, but preferably quarterly, updates to the drug reimbursement rates under the CAP. CMS will be updating the corresponding reimbursement rates for drugs acquired by doctors through the ASP + 6% system on a quarterly basis. If CMS only updates the CAP reimbursement rates on an annual basis there could be serious discrepancies in the reimbursement amounts for the two parts of the Part B program in the physician office. CMS should consider options to update the CAP drug prices on a more frequent basis than the annual schedule described in the proposed rule.

V. Other Issues Not Directly Addressed in the Proposed Rule

A. Fallback Option for Physicians Seeking the CAP. There may be certain areas of the country where few, if any, specialty pharmacy vendors choose to participate in the CAP program in 2006. As a result, some physicians who are seeking to get out of the drug acquisition business may not have the option to obtain their Part B drugs through the CAP program.

J&J Recommendation: To address this situation, CMS should develop a "fallback" option for physicians who do not have access to a CAP vendor. Such an option would help assure that physicians in certain regions of the country without potential CAP vendors may choose to have drugs provided through a vendor-like arrangement rather than having to incur the costs of a drug acquisition system themselves. J&J would be willing to have additional discussions with CMS staff to develop potential fallback options.

B. Bad Debt Reimbursement for Uncollected Coinsurance. The ultimate success of CAP will depend in large part on the degree of vendor interest in the program. Potential stumbling blocks to vendor interest are the proposals related to the collection of beneficiary coinsurance. Under the proposed program, the vendor is responsible for collecting deductibles and coinsurance, even though it will never be in direct contact with patients. Likewise, vendors are prohibited from seeking coinsurance until the physician drug administration claim and the vendor drug claim are reconciled within the CMS claims processing system. This could result in vendors having to wait several weeks before having the opportunity to even seek the coinsurance. As a result of the lack of direct contact with the patient and the lag time between drug administration and eventual CMS processing of the drug claim, vendors may often find themselves unable to collect the patient coinsurance. This could result in a substantial financial loss for the vendors as coinsurance represents several thousands of dollars in the annual reimbursement rate for some Part B drugs and biologics.

J&J Recommendation: Like it does for certain other providers in the Medicare program, CMS should consider establishing a policy to reimburse vendors for at least a portion of the bad debt they experience as a result of participating in the program. It could also consider adjusting the ASP + 6% composite bid limit to take into account the fact that vendors will lose a certain portion of the bid to bad debt.

C. Additional Burdens on Physicians Electing CAP. We have learned from physicians that there is widespread disagreement with the assertion in the proposed rule that the CAP will not create additional burdens. Physicians who elect to participate will be bearing certain costs specific to CAP that are not covered by the complex infusion fees or other existing mechanisms, such as:

1) Costs associated with maintaining an inventory safety stock;
2) Software costs plus administrative tracking costs associated with accommodating the new prescription number requirement, which is proposed to be a different number for each dose for the same patient over a course of therapy;
3) Related costs of exchanging initial information with the government contractor who is responsible for the drug (when ordering) and submitting information about administration of the drug to the government contractor subsequent to treatment;
4) Related costs of multiple duplicated contacts when dosage amounts are changed upon the patient's arrival for treatment or the drug has been received for a patient's therapy but the patient does not arrive for treatment; and
5) Costs of maintaining a dual ordering and inventory system.

J&J Recommendation: CMS should consider establishing a management fee that it would pay to physicians who participate in the CAP to offset some of these added costs.

Conclusion: J&J appreciates the opportunity to submit comments and recommendations to CMS. We look forward to working with you and your staff to ensure that Medicare beneficiaries have meaningful access to Part B drugs and biologics under CAP. If you have any questions related to these comments, please contact Greg White at 202-589-1040.

Sincerely,

Kathy Buto

Kathy Buto
Vice President, Health Policy

Mental Health Drugs in the Competitive Acquisition Program

Opportunity to significantly enhance patient access to care

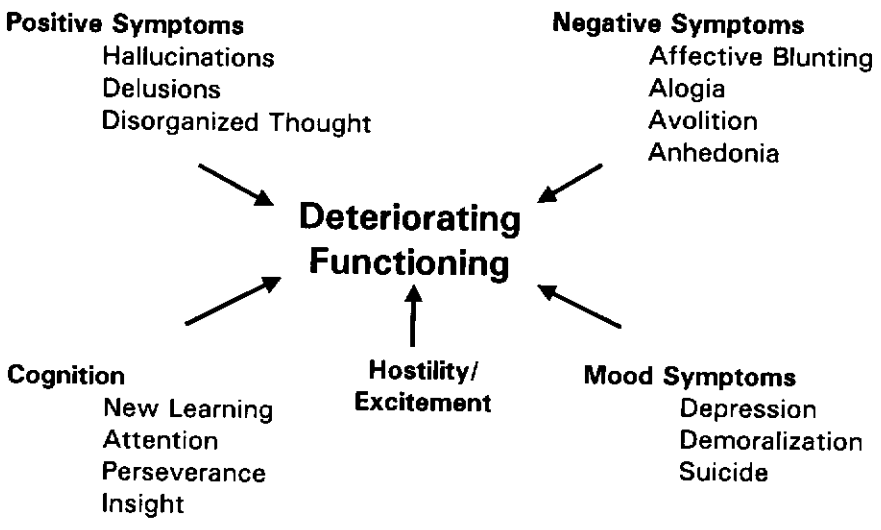
Competitive Acquisition Program

- Mental health drugs should be included in CAP at program launch (1-1-06)
- CAP should include as many drugs and in as many areas as possible:
  1. All drugs
  2. At a minimum include mental health and complex biologics

Discussion Topics

- Schizophrenia imposes tremendous societal burden
- Compliance is a major factor in managing the disease
- Long-acting injectables offer assured medication delivery
- Buy and bill process creates unintended access to care barriers
- Inclusion of mental health drugs in CAP provides an opportunity to enhance patients' access to care

Schizophrenia: Characteristics of the Illness



Schizophrenia: Burden of Illness to Society

- Schizophrenia is one of the most disabling disorders in the general population[1]
- The chronic nature of treatment has major health and economic significance[2]
- Many patients need antipsychotics for life[3]
- Compliance challenges limit the effectiveness of treatment

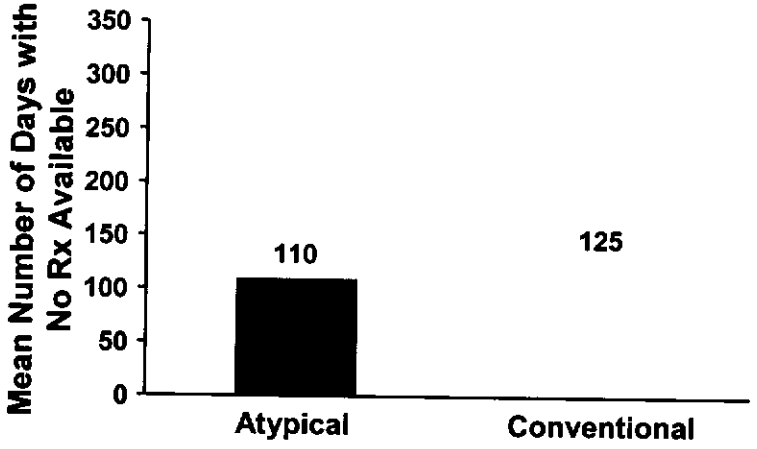
[1]Ustun et al. Lancet 1999
[2]WHO. The World Health Report 2001[3]Kessler R et al. Psych Med: 27 861-873, 1997.
[3]Davis JM, et al. Drugs 1994;47:741–73

Compliance with Medication Regimens for Mental and Physical Disorders

	Number of Studies	Follow-Up (Months)	Compliance Rates (SD)
Compliance with antipsychotic medication	24	3-24	58% (19)
Compliance with antidepressant medication	10	1.5-12	65% (18)
Compliance assessed with microelectronic monitoring among patients with nonpsychiatric disorders	12	0.25-10	76% (10)

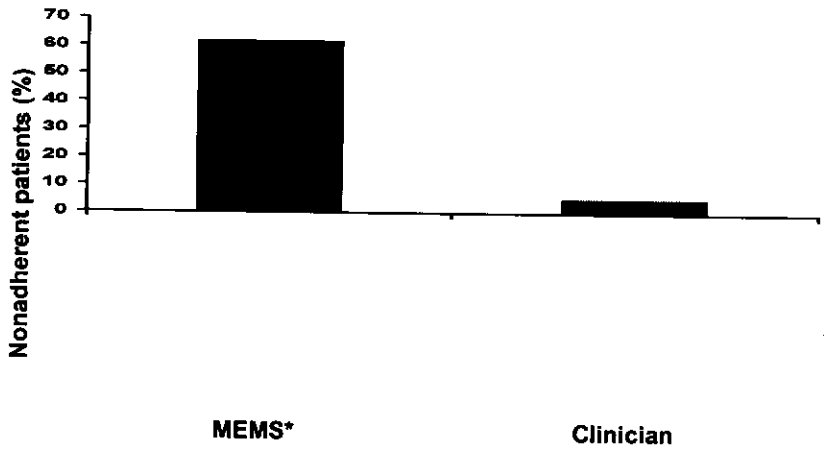
Cramer JA, Rosenheck R. Psychiatr Serv. 1998(Feb);49(2):196-201

Rx Refills of Antipsychotic Medication: 1-Year Naturalistic Study



Mahmoud RA et al. Poster presented at the 36th Annual Meeting of the ACNP; December 8-12; Kamuela, Hawaii; Janssen Pharmaceutica Products, L.P. 1997 (Data on file)

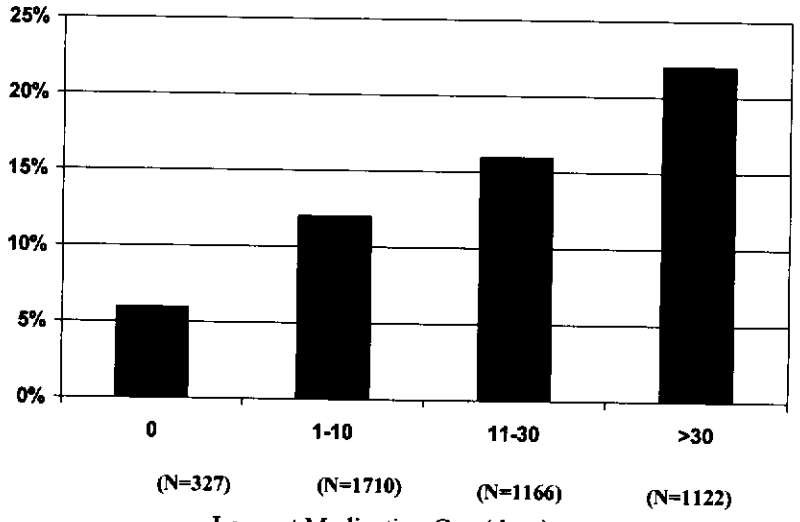
Its hard to tell which patients are non-adherent



*Electronic adherence monitoring device

Byerly M, et al. Presented at ACNP 2002, Puerto Rico

Partial Compliance and Hospitalization



Weiden PJ, et al. Psychiatr Serv. 2004 Aug; 55(8):886-91

Schizophrenia: Disproportionate Economic Impact

2002 National Statistics Inpatient Charges

	Schizophrenia (1.1%)	Hypertension (23.3%)
# of Discharges	282,884	237,380
Total Charges ($ Billions)	$5.18	$5.30
Payors: Medicare/ Medicaid	82.9%	75.0%

2002 National Hospital Statistics (HCUP database). Agency for Healthcare Research and Quality (AHRQ) website (http://hcup.ahrq.gov/HCUPnet.asp), accessed April 1, 2005

RISPERDAL® CONSTA®

- First long-acting injectable atypical antipsychotic
- Indicated for the treatment of schizophrenia
- Two week dosing interval
- Dosage range of 25 mg, 37.5 mg, 50 mg
- Water-based formulation

RISPERDAL® CONSTA® and the Impact on Institutional Psychiatric Care

Long-term Follow-up in Sweden

Eriksson L, Almqvist A, Mehnert, A, Eriksson B. Presented at the 42nd Annual Meeting of The American College of Neuropsychopharmacology. December 7-11, 2003, San Juan, Puerto Rico.

Trial Design and Objective

- **Objective**
  - Investigate differences in institutional care need before and during treatment
- **Methods**
  - Patients were participants in previous RISPERDAL® CONSTA® clinical trials who had received at least 3 injection cycles
  - Pre/Post design: Each patient served as own control
  - Post-period: time from the 1st to most recent injection
  - Pre-Period: identical time window prior to 1st injection
  - Total observation = pre-period + post/treatment
  - Pre-period data collection via chart abstraction at corresponding 29 Swedish hospitals

Source: Eriksson L et al. Presented at the 42nd Annual Meeting of The American College of Neuropsychopharmacology. December 7-11, 2003, San Juan, Puerto Rico.

Study Limitations

- Data are derived from an open-label extension non-U.S. study
- There was no active comparator group, only patients who were receiving ongoing treatment with RISPERDAL® CONSTA® were included in the analysis
- Not all participating hospitals were able to provide information on hospital bed availability during the study period
- Future studies are needed to confirm findings

Eriksson L et al. Presented at the 42nd Annual Meeting of The American College of Neuropsychopharmacology. December 7-11, 2003, San Juan, Puerto Rico.

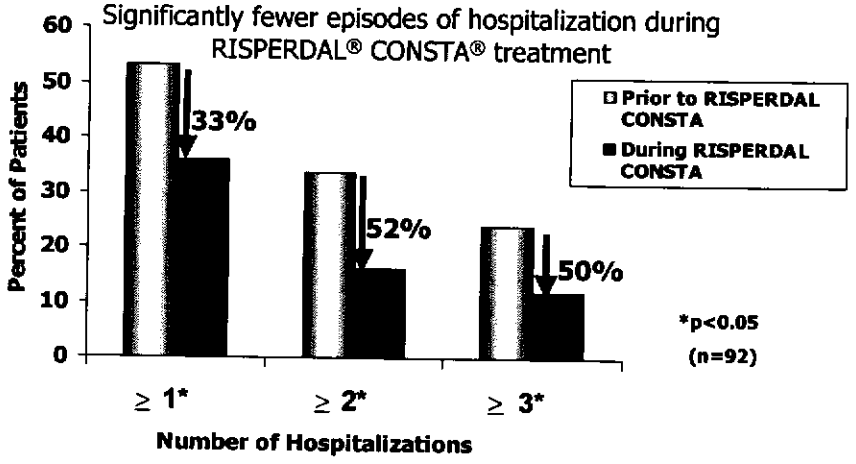
Demographics

Sample size	92
% Male	64%
Average age (at start of RISPERDAL® CONSTA® treatment)	47.6 years
Mean treatment time with RISPERDAL CONSTA	43 months (3.6 years)
Range of treatment time with RISPERDAL CONSTA	25 – 58 months

Eriksson L et al. Presented at the 42nd Annual Meeting of The American College of Neuropsychopharmacology. December 7-11, 2003, San Juan, Puerto Rico.

Risperdal CONSTA

Rehospitalization Rates



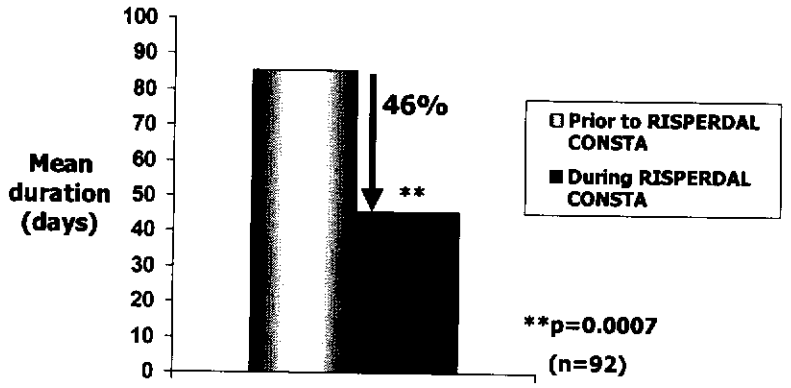
Data is derived from an open-label extension study where there is no comparator group.

Eriksson L et al. Presented at the 42nd Annual Meeting of The American College of Neuropsychopharmacology. December 7-11, 2003, San Juan, Puerto Rico.

Risperdal CONSTA

Mean Duration of Hospitalization

The mean duration of hospitalization decreased significantly by 46% during treatment with RISPERDAL® CONSTA®



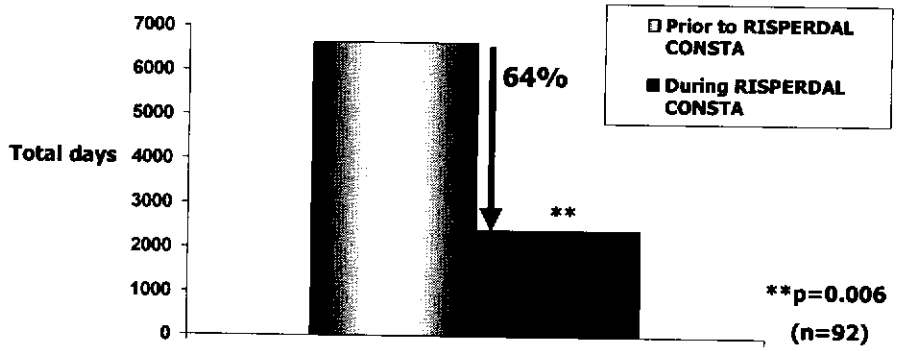
Taking into account a decrease in hospital bed availability of 21.6% (Data on file), the mean duration of inpatient care decreased by 35% (p=0.008).

Data is derived from an open-label extension study where there is no comparator group.

Eriksson L et al. Presented at the 42nd Annual Meeting of The American College of Neuropsychopharmacology. December 7-11, 2003, San Juan, Puerto Rico.

Total Population Days of Inpatient Care

Inpatient care across the total population decreased by 64% during RISPERDAL® CONSTA® treatment



Taking into account a decrease in hospital bed availability of 21.6% (Data on file), the total duration of inpatient care decreased by 56% (p=0.0156).

Data is derived from an open-label extension study where there is no comparator group.

Eriksson L et al. Presented at the 42nd Annual Meeting of The American College of Neuropsychopharmacology. December 7-11, 2003, San Juan, Puerto Rico.

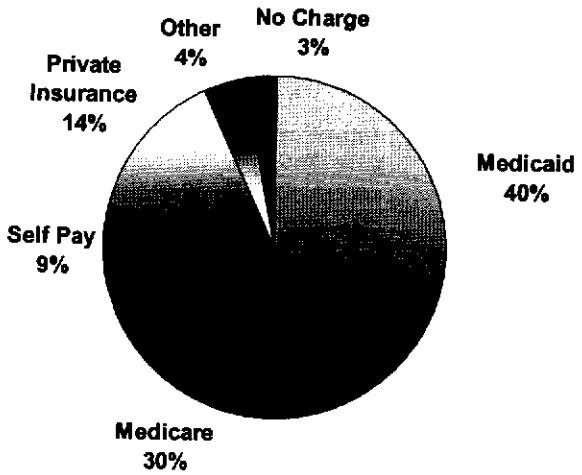
Conclusions

- Over a treatment period of at least 2 years, compared with a similar length period preceding treatment with RISPERDAL® CONSTA®, a switch to RISPERDAL CONSTA reduced
  - Number of hospitalizations
  - Duration of hospitalizations

Eriksson L et al. Presented at the 42nd Annual Meeting of The American College of Neuropsychopharmacology. December 7-11, 2003, San Juan, Puerto Rico.

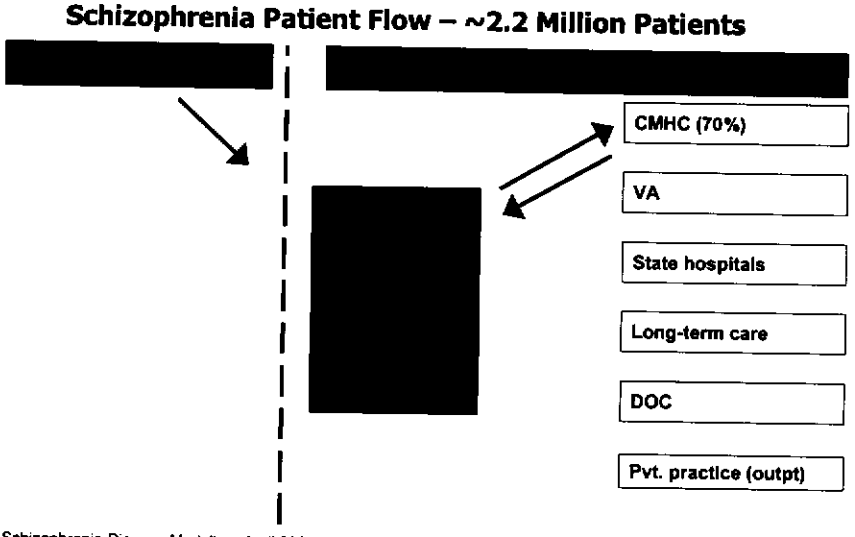
Schizophrenia: Reimbursement Mix

Outpatient Setting



NAMCS and NHAMCS, 1997-2000 Nationalized Survey Data

Community Mental Health Centers (CMHCs): Primary Treatment Sites for Schizophrenia Patients



McKinsey Schizophrenia Disease Modeling, April 2002

Community Mental Health Centers

- Primary outpatient treatment sites for mentally ill and substance abusers
- Serve clients regardless of ability to pay
  - –La rgely not for profit organizations
- Internal structure, size, budget, and services offered varies greatly
- Overwhelming majority of funding is public funding

Physician Frustration with "Buy & Bill"

Why are Physicians frustrated?

- **Confusion** about the reimbursement process and payer responsibility
- **Uncoordinated** CMHC office staff
- **Resistance** to Buy & Bill
- **Impatience** with unfamiliar process

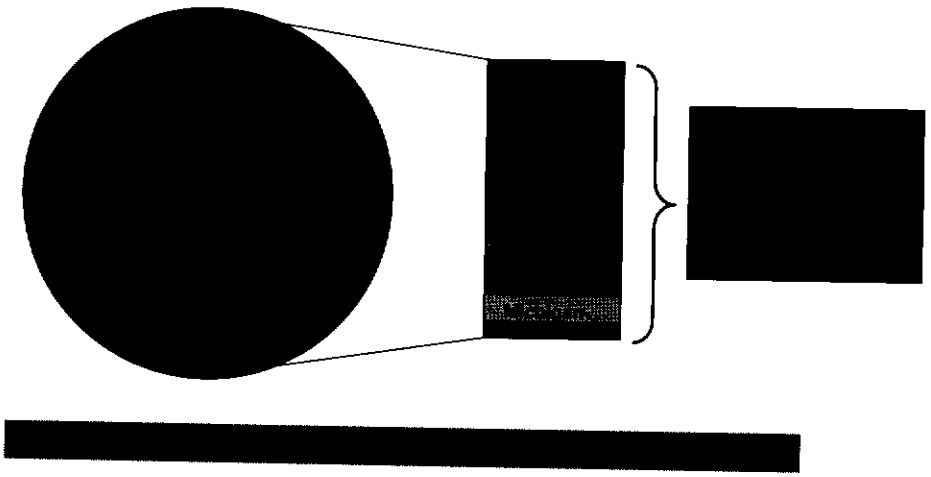
"...the arrival of RISPERDAL CONSTA was a much anticipated event...anticipation has given way to frustration and anger...what I can not deal with is the paperwork burden, the uncertainty of knowing if a patient is eligible for the drug, the lag time between patient consent and drug administration...based on my experience with forms to Medicaid, forms to the indigent program, faxing, refaxing, clarifying errors in form completion...I would need at least a quarter time clerical person to support 25 persons actually receiving RISPERDAL CONSTA. There is no such person. It's all doctor time...."

- M. Amdur, MD, Medical Director, Thresholds

Case example

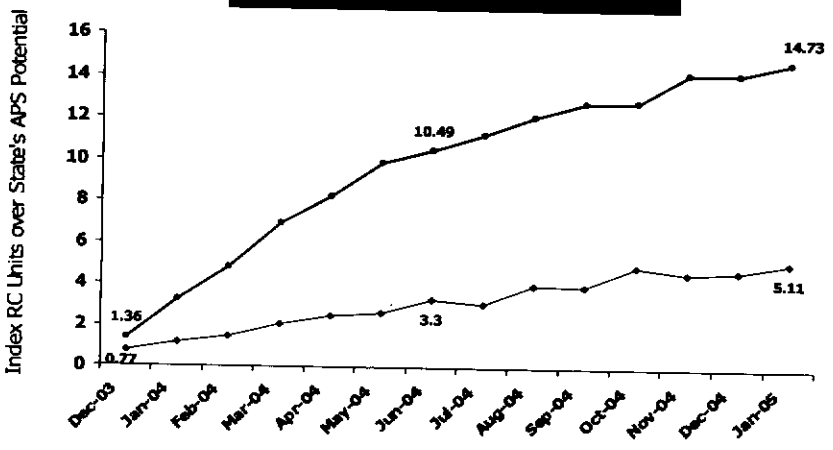
- Overview:
  - County contracted psychiatrist with a high volume of severely mentally ill
  - Placed 196 consumers on therapy
  - Hired one FTE to help support use
- Issues:
  - Office coded incorrectly - 40 denied claims to Medicare carrier
  - Timing of reimbursement did not coincide with distributor payment
  - Provider in arrears with distributor ($70K)
- Outcome:
  - Removed 196 consumers from therapy
    - Recently reinitiated therapy with 12 consumers via pharmacy benefit

Impact on Clinical Trial Participation



Reimbursement approach effects access to RISPERDAL CONSTA

Ris Consta Index [RC Units / State Potential (% of APS)]



Source: IMS DDD Retail & Non-Retail

Discussion Topics

- Schizophrenia imposes tremendous societal burden
- Compliance is a major factor in managing the disease
- Long acting injectables offer assured medication delivery
- Buy and bill process creates unintended access to care barriers
- Inclusion of mental health drugs in CAP provides an opportunity to enhance patients' access to care

Competitive Acquisition Program

- Mental health drugs should be included in CAP at program launch (1-1-06)
- CAP should include as many drugs and in as many areas as possible:
  1. All drugs
  2. At a minimum include mental health and complex biologics

Safety Considerations

Commonly observed events: Treatment-emergent adverse events with an incidence of 5% or greater in at least one of the RISPERDAL CONSTA groups (25 mg or 50 mg) and at least twice that of placebo were: somnolence, akathisia, parkinsonism, dyspepsia, constipation, dry mouth, fatigue and weight increase.

Hyperglycemia & Diabetes: Hyperglycemia, some cases extreme and associated with ketoacidosis, hyperosmolar coma or death has been reported in patients treated with atypical antipsychotics (APS), including RISPERDAL CONSTA. Patients starting treatment with APS who have or are at risk for diabetes, should undergo fasting blood glucose testing at the beginning of and during treatment. Patients who develop symptoms of hyperglycemia should also undergo fasting blood glucose testing.

Tardive dyskinesia: As with all antipsychotic medications, prescribing should be consistent with the need to minimize the risk of tardive dyskinesia; if its signs and symptoms appear, discontinuation of RISPERDAL CONSTA should be considered. In the integrated database of multiple-dose studies the incidence of tardive dyskinesia was 0.6% (9/1499 patients).

NMS: Neuroleptic malignant syndrome (NMS) has been reported rarely with this class of medications, including RISPERDAL CONSTA and appropriate management should be employed.

Safety Considerations

Cerebrovascular adverse events (CAEs): Cerebrovascular adverse events (CAEs), including fatalities, have been reported in elderly patients with dementia-related psychosis taking oral risperidone in clinical trials. The incidence of CAEs with oral risperidone was significantly higher than with placebo. RISPERDAL CONSTA is not approved for treating these patients.

Maintenance treatment: Patients should be periodically reassessed to determine the need for continued treatment.

Extrapyramidal symptoms: The overall incidence of EPS-related adverse events in patients treated with 25 mg & 50 mg of RISPERDAL CONSTA and placebo respectively, were akathisia (2%, 9%, 4%), parkinsonism* (4%, 10%, 3%) and tremor (0%, 3%, 0%). *Bradykinesia, extrapyramidal disorder, and hypokinesia.

Additional considerations for special populations: Limited clinical trial data are available in elderly, renally or hepatically impaired patients, and RISPERDAL CONSTA should be used cautiously in these patients.

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention; CMS-1325P
PO Box 8010
Baltimore, MD 21244-8010

4-22-05

regarding : Medicare Part B- Competitive Acquisition of Outpatient Drugs and Biologicals

To whom it may concern,

I am a RN in an outpatient Mental Health Clinic.I have heard about the proposed rule that would implement CAP. I would like see CMS include pschiatric drugs in the initial stages of CAP and have a category that includes mental health drugs. Our facility effectively uses long-acting injectable antipsychotics which we sometimes purchase under a buy and bill process. CAP could provide a second ooption in acquiring this medication for Medicare eligible consumers. This would reduce the time and paperwork that is required in accessing these medications.

Sincerely,

C Mckelvey

Cynthia Mckelvey, RN